

PhUSE SEND Industry Survey

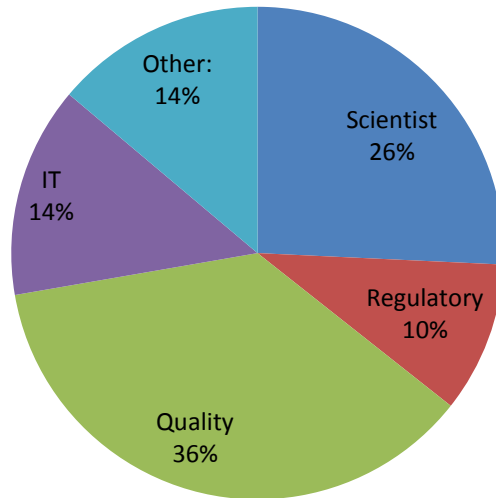
Survey: PhUSE SEND Industry Survey 2016

What country are you located in?

Count	Response
1	Armenia
1	Canada
2	China
2	Denmark
5	Germany
1	Globally
1	INDIA
4	India
8	Japan
2	Singapore
2	Switzerland

1	Taiwan
3	UK
12	US
40	USA
15	United States
3	United States of America
1	Unites States
1	Usa
1	canada
1	italy
1	japan
3	usa

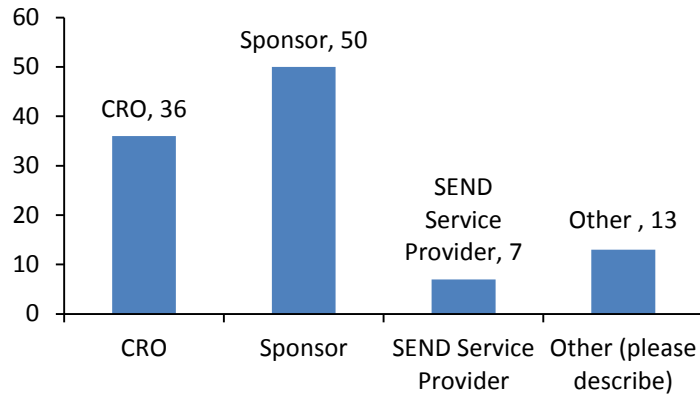
What is your primary job area?



Value	Percent	Count
Scientist	26.1%	29
Regulatory	9.9%	11
Quality	36.9%	41
IT	13.5%	15
Other:	13.5%	15
Total		111
Responses"Other:"		Count
Left Blank		98

Audit labs (GLP and GCLP)	1
Business System Administrator	1
Compliance	1
Consultancy	1
Data management	1
Date Management	1
Management	2
Operations	1
Project Planning	1
Reports	1
SEND Architects	1
management; vendor	1

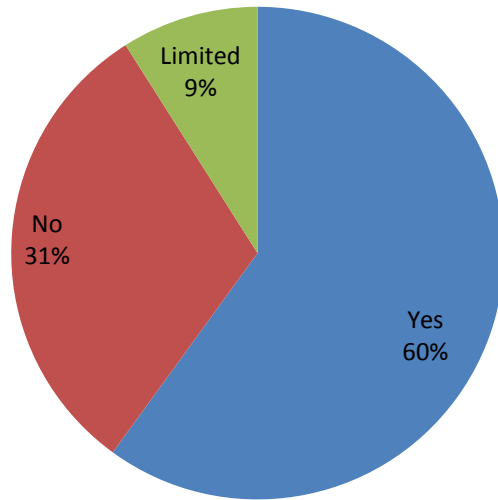
1. Demographic: Is your organization primarily a (select all that apply):



Value	Percent	Count
CRO	36.0%	40
Sponsor	50.5%	56
SEND Service Provider	7.2%	8
Other (please describe)	12.6%	14
Total		111
Responses "Other (please describe)"		Count
Left Blank		97
Consultant		3
Consulting		1
Contaminants Laboratory		1

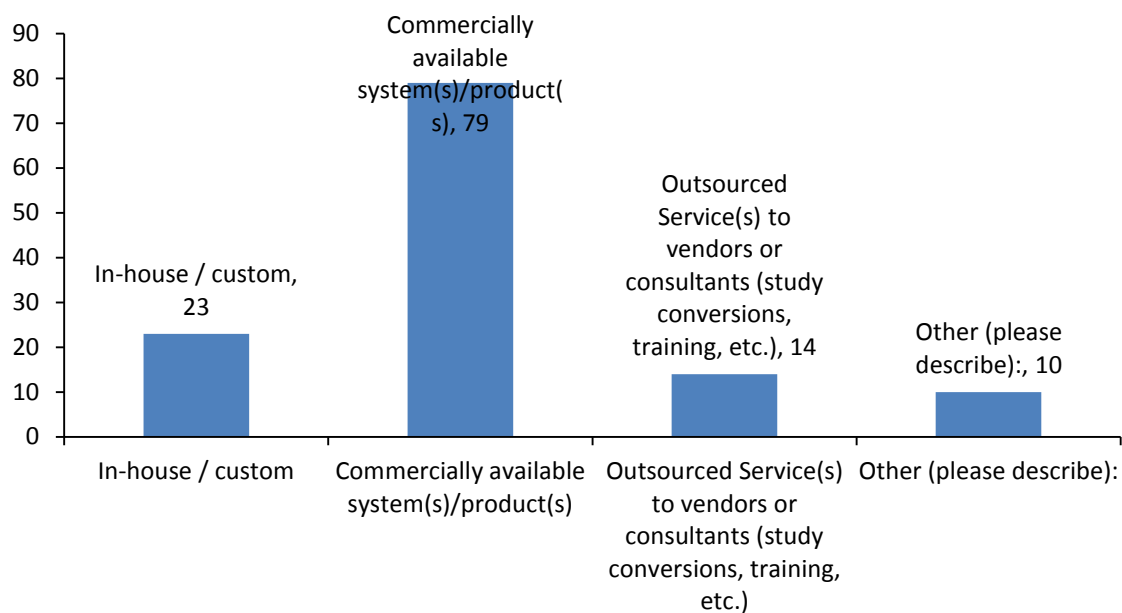
Contract Testing Laboratory	1
Corporate R&D	1
Federal contractor providing lab audit support.	1
Pharma	1
Pharmaceutical R & D	1
QA/QC Consultant	1
Regulatory Consultant	1
Research Facility	1
academic institution	1

2. Do you run studies in-house that will be submitted to FDA?



Value	Percent	Count
Yes	60.4%	67
No	30.6%	34
Limited	9.0%	10
Total		111

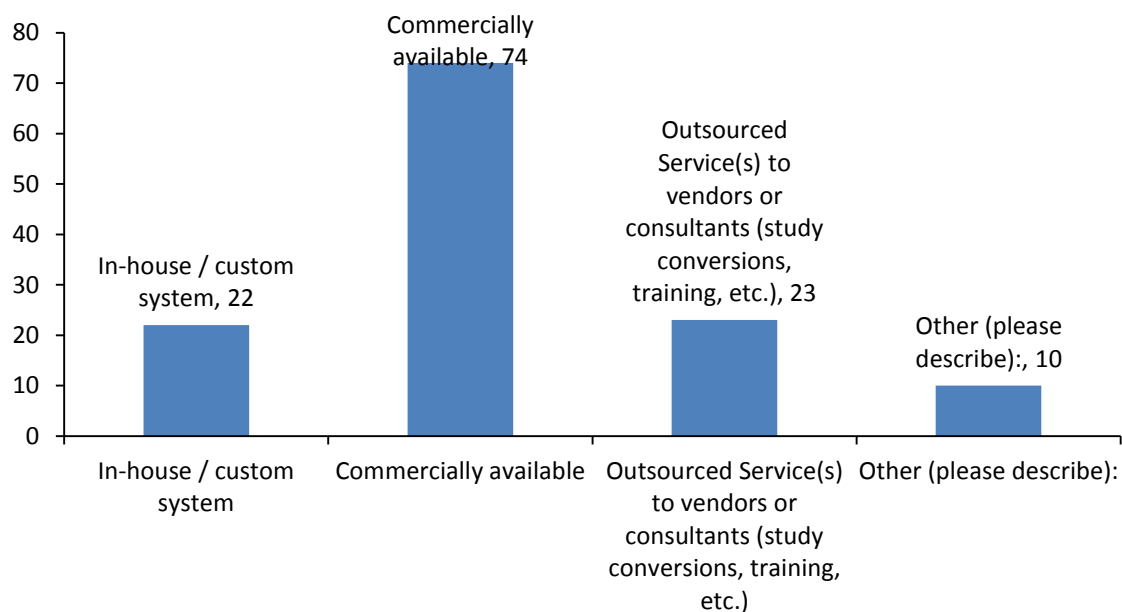
For Nonclinical Drug Safety/ General Toxicology (select all that apply):



Value	Percent	Count
In-house / custom	23.4%	18
Commercially available system(s)/product(s)	79.2%	61
Outsourced Service(s) to vendors or consultants (study conversions, training, etc.)	14.3%	11
Other (please describe):	10.4%	8
Total		77
Responses"Other (please describe):"		Count
Left Blank		103

N/A	1
No LIMS	1
None	2
SEND format not adopedated till. Currently, report table design manually.	1
none	2
we are considering to buy the part for pathologist first.	1

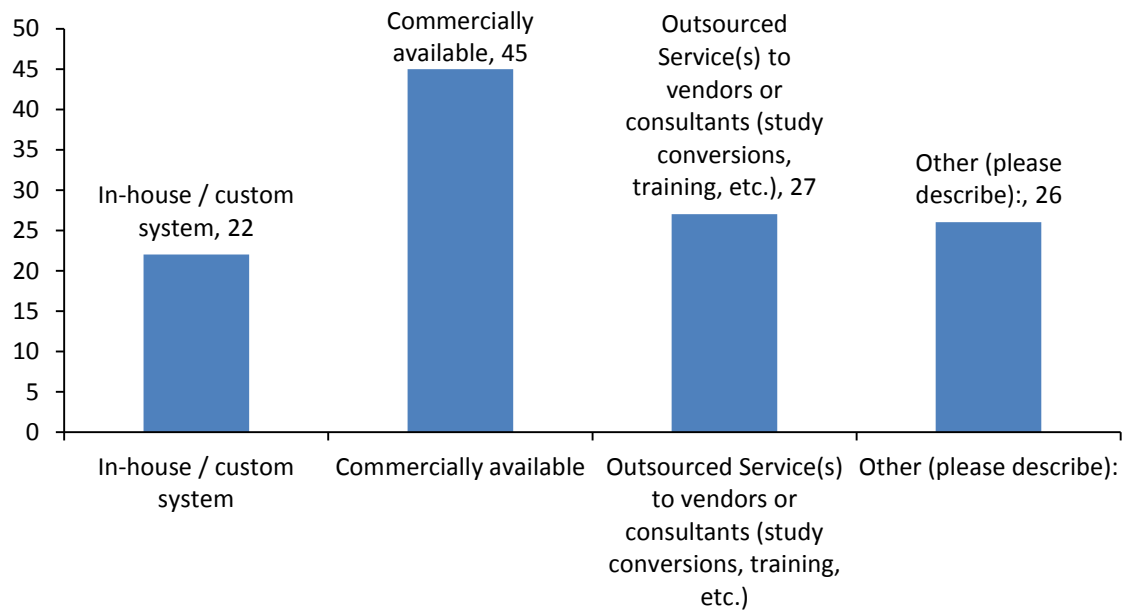
For DMPK and Analytical (select all that apply):



Value	Percent	Count
In-house / custom system	22.1%	17
Commercially available	74.0%	57
Outsourced Service(s) to vendors or consultants (study conversions, training, etc.)	23.4%	18
Other (please describe):	10.4%	8
Total		77
Responses "Other (please describe):"		Count
Left Blank		103
Commercially available with in-house customization		1

No LIMS	1
Non LIMS user	1
Not applicable in our facility	1
SEND format not adopedated till. Currently, report table design manually.	1
Some bioanalytical done internarly	1
no LIMS - manual data, ChemStation, Analyst, and WinNonlin	1
none	1

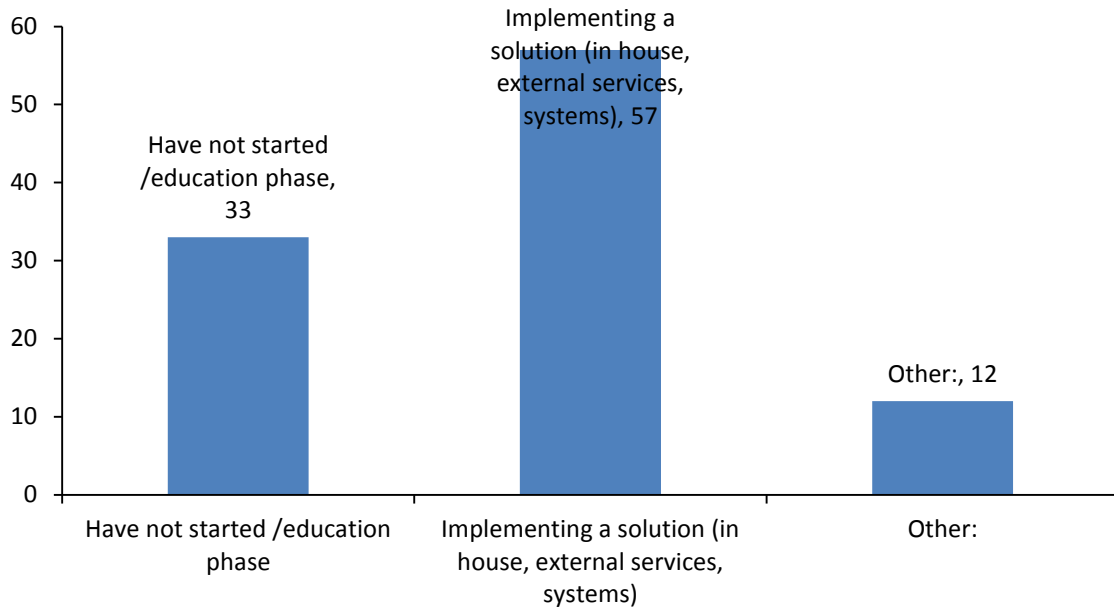
For Repro/DART (select all that apply):



Value	Percent	Count
In-house / custom system	22.1%	17
Commercially available	45.5%	35
Outsourced Service(s) to vendors or consultants (study conversions, training, etc.)	27.3%	21
Other (please describe):	26.0%	20
Total		77
Responses "Other (please describe):"		Count
Left Blank		91
Don't do these or need them		1

I don't understand	1
Manually captured	1
N/A	2
NA	4
Ni LIMS	1
Non LIMS user	1
Not applicable	1
Not applicable in our facility	1
Not performed in house	1
Outsourced to CROs	1
SEND format not adopted till. Currently, report table design manually.	1
Some manual data which we are trying to address with commercially available software	1
none	3

3. What stage of SEND readiness are you in? (select all that are appropriate)

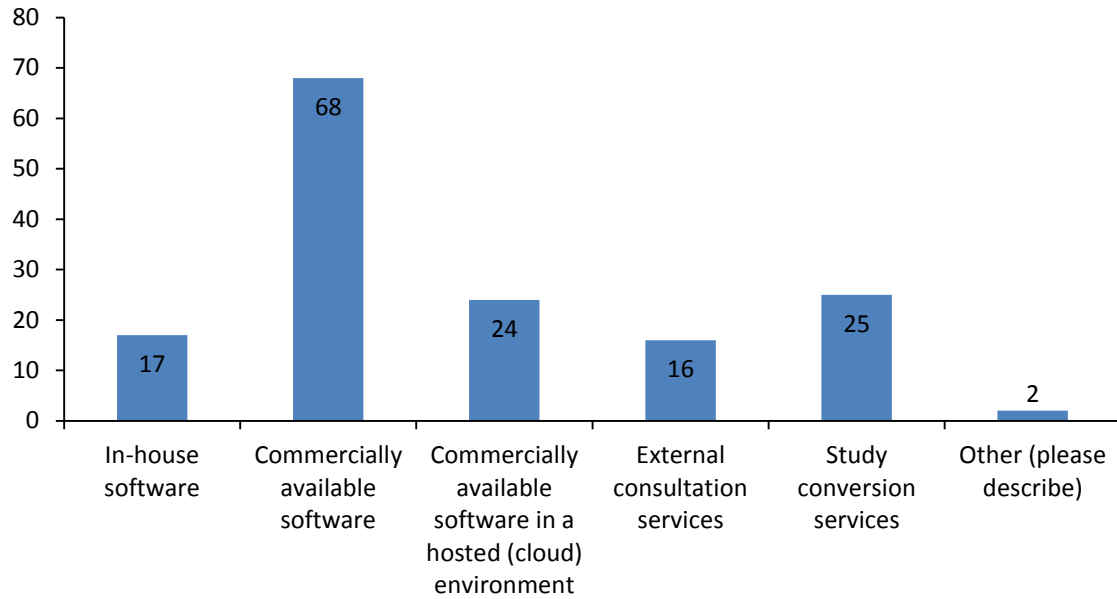


Value	Percent	Count
Have not started /education phase	33.3%	37
Implementing a solution (in house, external services, systems)	56.8%	63
Other:	11.7%	13
Total		111
Responses "Other:"		Count
Left Blank		98
CRO ready		1

Consultation to users	1
Education for client advisement	1
Looking at options	1
Piloting a commercial system	1
SEND Services Provider with solutions and services	1
SEND implementation complete	1
Solution implemented, now refining and enhancing to generate complete datasets	1
Submit	1
Tool validated; currently mapping translations between Provantis and the Submit module.	1
Validation	1
We audit labs so need to understand SEND from that perspective.	1
We don't have studies; our clients are mixed with respect to their SEND readiness	1

Please tell us about the system(s) you are implementing

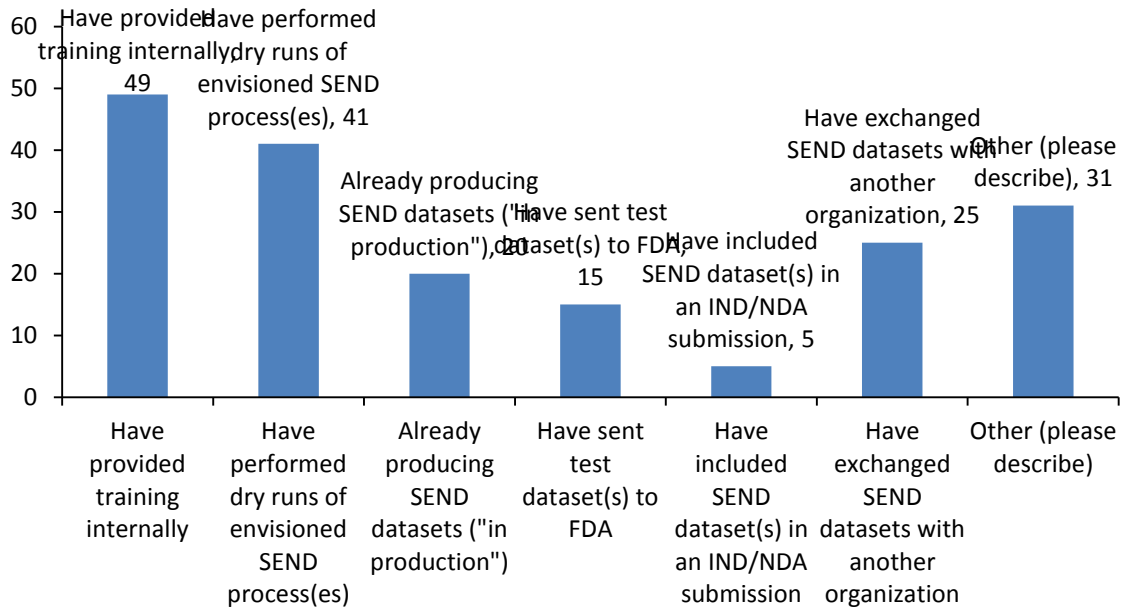
(select all that apply):



Value	Percent	Count
In-house software	17.5%	11
Commercially available software	68.3%	43
Commercially available software in a hosted (cloud) environment	23.8%	15
External consultation services	15.9%	10
Study conversion services	25.4%	16
Other (please describe)	1.6%	1
Total		63

Responses"Other (please describe)"	Count
Left Blank	110
Customized commercial software	1

4. What actions are you currently taking / have taken towards implementation? (select all that apply)



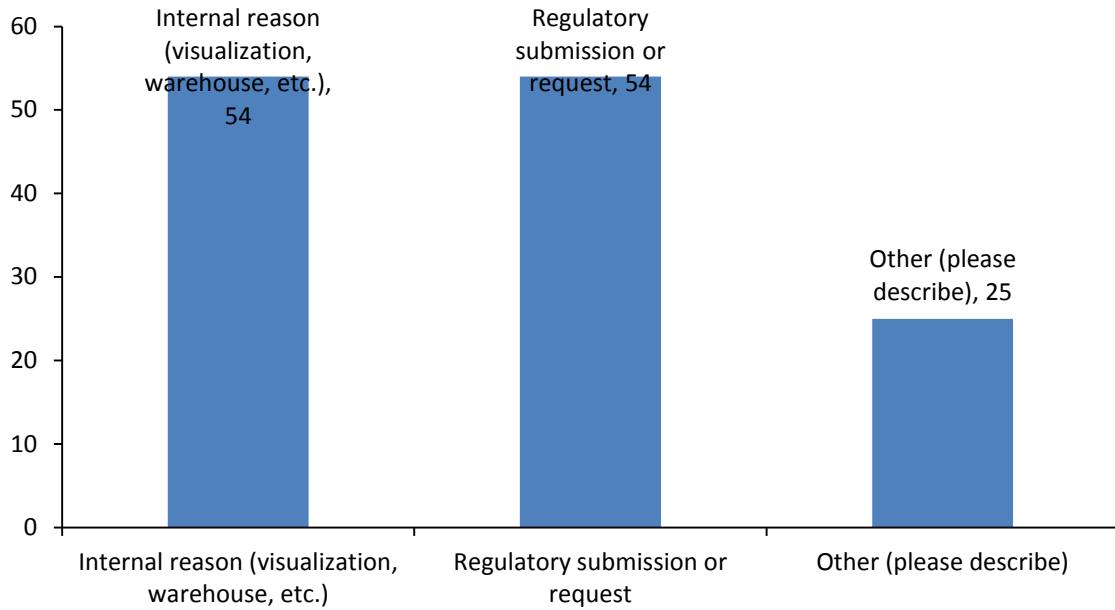
Value	Percent	Count
Have provided training internally	48.7%	54
Have performed dry runs of envisioned SEND process(es)	40.5%	45
Already producing SEND datasets ("in production")	19.8%	22
Have sent test dataset(s) to FDA	15.3%	17
Have included SEND dataset(s) in an IND/NDA submission	4.5%	5
Have exchanged SEND datasets with another organization	25.2%	28

Other (please describe)	30.6%	34
Total		111
Responses"Other (please describe)"		Count
Left Blank		77
Consulted with SEND solution provider		1
Developing awareness		1
Have evaluated several potential providers (vendors) of SEND solutions		1
Have not started at all.		1
Helped our clients work with their SEND data		1
Learning more about SEND.		1
NA		2
No action taken		1
No action to date, analytical testsTest		1
No actions		1
No one has taken any action		1
None		1
None at present		1

None of the above.	1
Preparing manuals	1
SEND solutions provider with complete set of products and services	1
Still in planning phase	1
Thinking about it	1
We have SDTM and ADaM in place but not SEND yet	1
aware but no action taken yet	1
design phase	1
electronic submission	1
learning how to implement and what needs to be completed	1
no steps taken at this time	1
none	2
none so far	1
reviewing available information for pathology SEND datasets	1
studying the regulatory guides	1
validated SEND solution	1
waiting for validation/installation of SEND software by commercial vendor	1

Scheduled for this spring/summer upon completion of validating data collection system (almost completed).	1
Currently working on developing an outsourced model for dataset generation and services as well as a pilot	1

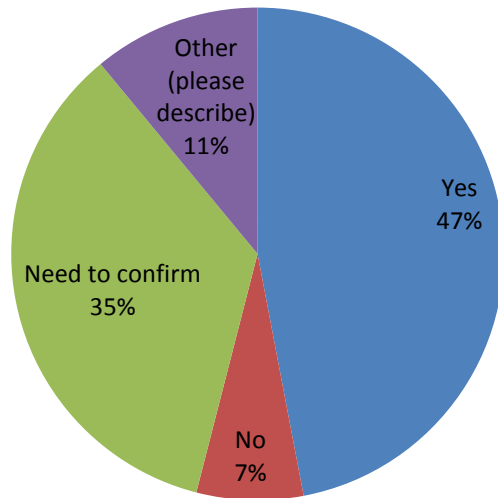
What was the purpose of the dataset exchange? (select all that apply)



Value	Percent	Count
Internal reason (visualization, warehouse, etc.)	53.6%	15
Regulatory submission or request	53.6%	15
Other (please describe)	25.0%	7
Total		28
Responses "Other (please describe)"		Count
Left Blank		104
Client doing pilot submission		1
Pilot of regulatory submission		1

Piloting	1
System User Group Sharing	1
Test Submission	1
Testing	1
To consult SEND expert if datasets are in accordance with FDA SEND requirements	1

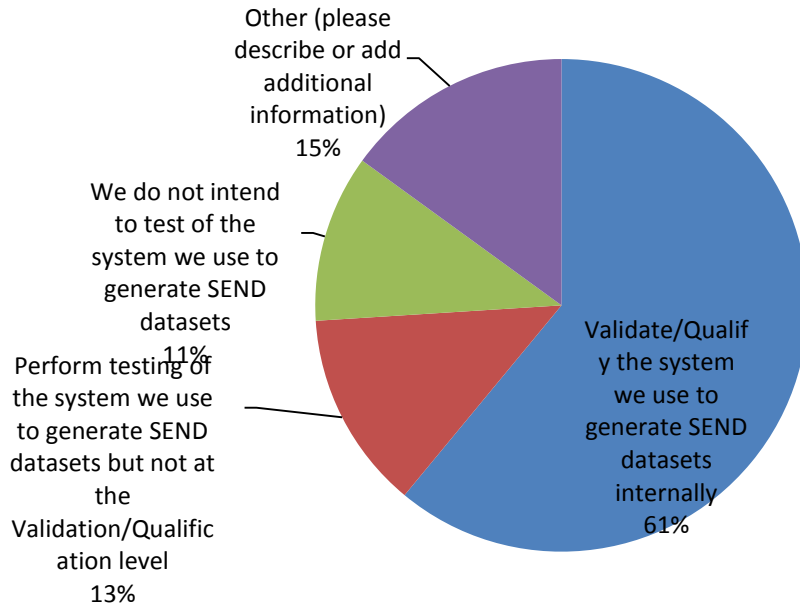
5. Are your service providers able to create SEND datasets or have a plan in place to do this in the right timeframe?



Value	Percent	Count
Yes	46.9%	52
No	7.2%	8
Need to confirm	35.1%	39
Other (please describe)	10.8%	12
Total		111
Responses "Other (please describe)"		Count
Left Blank		99
Don't know		1

I don't know	1
Mixed responses from vendors	1
Most are ready	1
N/A	1
NA	1
We are a SEND solutions provider with complete set of products and services	1
We would query the labs.	1
Yes for larger CROs	1
mixed, some ready, some are not	1
we are the service provider and have a plan to do this in the right timeframe	1
we do not believe there is a timeframe within which we must comply due to the nature of our work	1

6. With regard to your company's implementation of a SEND computer system(s), at what level do you intend to test the system?



Value	Percent	Count
Validate/Qualify the system we use to generate SEND datasets internally	61.3%	68
Perform testing of the system we use to generate SEND datasets but not at the Validation/Qualification level	12.6%	14
We do not intend to test of the system we use to generate SEND datasets	10.8%	12
Other (please describe or add additional information)	15.3%	17

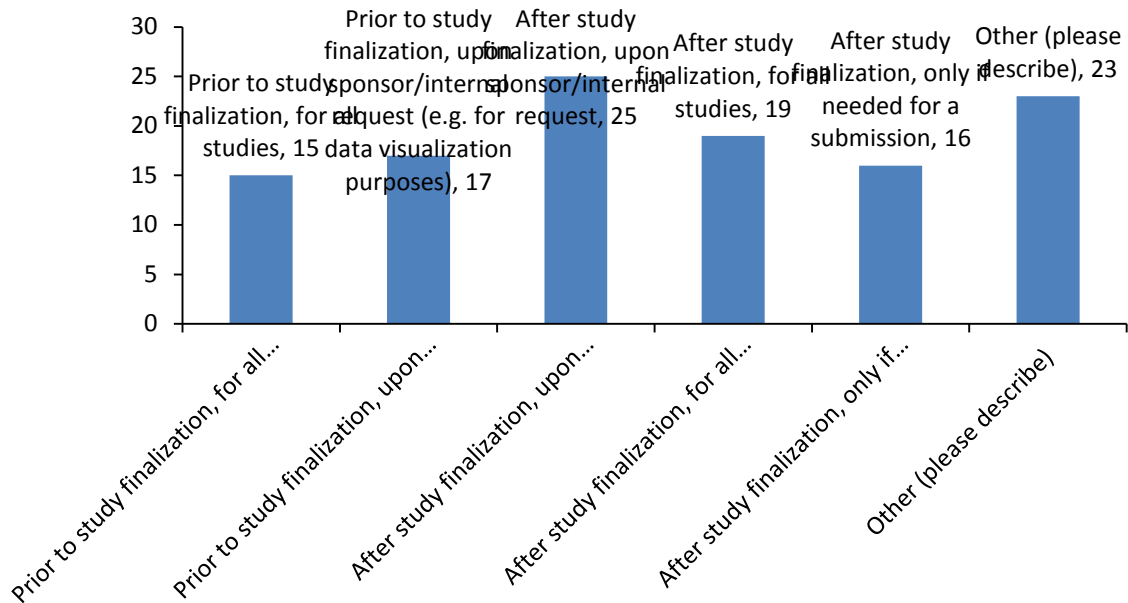
Total		111
Responses"Other (please describe or add additional information)"		Count
Left Blank		94
N/A		1
NA		1
No SEND dataset generated internally		1
None		1
Not considered yet		1
Perform QC checks on SEND datasets generated by CROs prior to submission to FDA		1
Provide data sets to sponsor		1
Send testing phase		1
TBD		1
Unknown at this time.		1
Unsure at this time		1
We intend to use a service, and will review their validation documentation.		1
We outsource generation of SEND datasets		1

We would assess a labs LIS/LIMS and capture their status in terms of validation/testing.	1
n/a	1
to be decided	1
validation/qualification to be done by commercial vendor	1

Please provide more information:

Count	Response
1	Currently in the vendor (SEND services/software) evaluation phase.
1	Vendor supplied solution
1	We would be doing 100% QC of all output at this point
1	Is it mandatory to use automation (computer system) to implementation of SEND ? Can we adopt SEND for manual report designing ?

7. At what point related to study finalization (report signed by Study Director) does your company plan to generate SEND datasets? (select all that apply)



Value	Percent	Count
Prior to study finalization, for all studies	15.3%	17
Prior to study finalization, upon sponsor/internal request (e.g. for data visualization purposes)	17.1%	19
After study finalization, upon sponsor/internal request	25.2%	28
After study finalization, for all studies	18.9%	21
After study finalization, only if needed for a submission	16.2%	18

Other (please describe)	22.5%	25
Total		111
Responses"Other (please describe)"		Count
Left Blank		86
Still undecided		1
Have not yet decided.		1
I currently do not know.		1
Internal team has not made this decision yet.		1
N/A		1
NA		1
No being done here		1
None		1
Not applicable for us.		1
Not considered yet		1
Not decided yet		1
Not sure		1
SEND solutions provider with complete set of products and services		1

Sorry	1
TBD	1
Under consideration	1
Unsure at this time	1
don't know	1
not discussed yet	1
not sure yet	1
prior to finalization if needed for a submission	1
still deciding	1
to be decided	1
unknown	1
After finalization for all studies with potential for future submission. Exploratory studies are not processed.	1

8. What is the rationale for your timing decision in question #7 above? (describe)

Count	Response
1	After finalization will lesson the chance of raw data changing during dataset creation
1	As per sponsor's request
1	As study director needs to interpret the results prior to study completion date.
1	Avoid separate Quality assurance step
1	Best guess right now
1	Business priority
1	CRO ready; send if needed.
1	Clients primarily CRO with no direct influence on SEND
1	Convenience
1	Cost and Workload
1	Cost issue
1	Data in SEND format is not part of the final report.
1	Datasets are needed to make clinical decisions

1	Datasets will be generated while study conduct is contemporary.
1	Don't want to finalize the study and then produce data set which could have errors and warnings
1	Following FDA SEND guidance
1	For GLP studies any modification after SD sign require Report amendment.
1	GLobal agreement as to what most Sposnors ask for
1	I can not explain
1	I currently do not know what will be done; therefore, I have no answer for this question.
1	If the study is not going to be submitted, we currently do not see a reason for using SEND.
1	Industry
1	It has not been discussed within our company or with our Vendors/CRO's
1	Its only a packaging of study data, and wont be conducted for every study
1	Its whats required
1	Just based on internal discussion
1	Leverage SEND data sets for internal study data review during

	study and in writing report.
1	Making data available to internal scientists asap.
1	Management
1	Management is unaware
1	Match required deliverables to client requests
2	N/A
1	NIL
1	None
1	Not all studies will be submitted to FDA.
1	Not applicable
1	Not considered yet
1	Not sure
1	Purely sponsor/client driven.
1	SEND Datasets will be generated after the data is completed in the LIMS System.
1	SEND data will not be used for in-house interpretation of data.
1	Safest timeline

1	Still in discussion
1	Still in learning phase.
1	Still in the learning phase about implementation of SEND.
1	Study needs to be finished before starting send process
1	The development plan
1	The process is still in discussion and has not been finalized.
1	The study datasets will be used for populating a datawarehouse.
1	To make the study is on going on time
1	To minimize effort
1	Under consideration
1	We are a CRO we need to have options available for our sponsors
1	We are a SEND solutions provider with complete set of products and services
1	We are still evaluating which studies we plan to generate SEND datasets.
1	We audit as opposed to conduct preclinical studies.
1	We still have not made a definitive decision on when to generate SEND datasets.

1	Will depend on circumstances.
1	based on protocol
1	data warehous
1	discussion the contract for study
1	finalization
1	n/a
1	na
1	no comment
1	none.
1	not sure
1	not sure yet
1	registration
1	resources
1	resources driven
1	retain existing reporting procedures while having all data stored centrally in SEND format.
1	that is decision at moment in time but may change/not glp requirement.

1	to allow for data interrogation
1	to be decided
1	to enable time for running datasets through the validator tool
1	too small and studies infrequent that require SEND
1	unknown
1	Generated prior to finalization to detect errors that can be corrected in source systems more easily before finalization, and in the future to use to assist with study interpretation. After study finalization for all studies that are considered useful for our data warehouse.
1	As per the request of client/sponsor; usually prior to finalization but possibly after finalization, if requested.
1	SEND is considered external to GLP, ISO process subject to validation and QC auditing prior to submission that requires Sponsor compliance statement for the package.
1	in order to ensure the datasets and the report match, the data must be extracted before finalization.
1	We only intend to do it when requested since our capabilities will include limited resources to spend on creating SEND datasets
1	We plan to apply the SEND system on 2017. We choose the outsourcing for SEND datasets depend on the sponser's request until then.

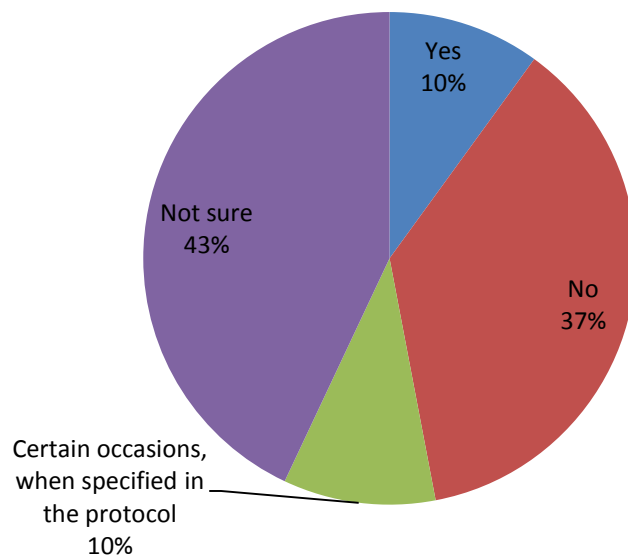
1	Shortly after finalization all Information is still "present" in the minds of all affected colleagues. It is much easier to build the study structure in our SEND System and to upload the correct files after study end than to wait until a Submission. We will store the SEND files together with the final Report, waiting to be used later.
1	Don't do a large number of studies to justify implementation across the board; most studies conducted at the main facility where I work are non-GLP
1	As a SEND service provider, we only generate SEND datasets on client request. This always happens after study completion, but not always due to submission. Some clients use SEND datasets for internal use.
1	Before finalization - for interim filings and for testing the final SEND product. After finalization - when all data has been audited.
1	To have all data QA/QC checked together with the finalization of the report - all done when the report is final
1	At the moment this meets the needs of our customers. It could change for the future and it is possible that SEND data sets will be produced prior to study finalisation.
1	Interim datasets will be used for visualization purposes, and final datasets will be used for relevant SEND required submissions. Going forward as the cost to receive datasets is better understood, we may ask for all studies to have SEND datasets.
1	Generation of SEND dataset is a sponsor (submission-based) requirement. Thus the need to generate such a set must be

	<p>driven by the sponsor. Datasets will not be generated until the study data have been audited and are therefore static.</p>
1	<p>To enable the correct data (after all changes and QA is complete) SEND data sets will be delayed until a complete audited data file is present.</p>
1	<p>SEND datasets can be prepared at anytime during a study if requested and data is available, however to manage workload and limit file management burden only studies that have a potential for future submission get a full workup.</p>
1	<p>At this time the final SEND dataset is sent after report finalization for studies in which it is requested. Drafts are prepared once the data is static in order to expedite the process.</p>
1	<p>Contract testing lab, perform analytical testing for small portion of study, one of many data sources feeding into final report</p>
1	<p>Study Sponsor / Internal should know which studies will be submitted to the FDA even before the completion of the study</p>
1	<p>since our studies are glp compliant medical device studies, our clients do not make submissions to cder or cber. They are also not applying for INDs or NDAs.</p>
1	<p>Need to verify the contents of SEND datasets created by our CROs prior to submission and do not want to wait for final report before starting this process</p>
1	<p>To mimic the reporting procedures, prevent delays in our clients' submission timelines, and we prefer to generate a draft dataset to identify and realize issues while the study is open.</p>

1	Prior to study finalization for input file-like datasets, after study finalization to account for any QA findings. We plan on doing this for all studies once implemented. Most efficient way.
1	After study finalization, for all studies to be on the safe side. Plus we do receive some SEND files from some CROs before final reports.
1	Prior to study finalization: interim SEND files are used for monitoring purposes with datavisualization tools and for scientific review once all data are available. This info is needed long before a report is finalized. These files would not be for submission though consideration needs to be made for when draft reports are submitted to the FDA i.e. as part of an IND with tight timelines. At Study Finalization: For final data storage and submission.
1	Datasets will be a requirement. The datasets will be submitted to the agency with the final report unless otherwise requested by the agency.
1	By generating SEND dataset after finalization we are defining it as a regulatory/submission activity. Prior to finalization it could be interpreted as a study activity.
1	We consider SEND datasets to be regulatory/submission documents, not study documents. If/when a Sponsor requests SEND datasets, we'll have a service produce them.
1	Datasets (xpt files) can be generated only after all the data, including histopathology, are finalized.
1	to run both test scenarios prior to gathering data and then

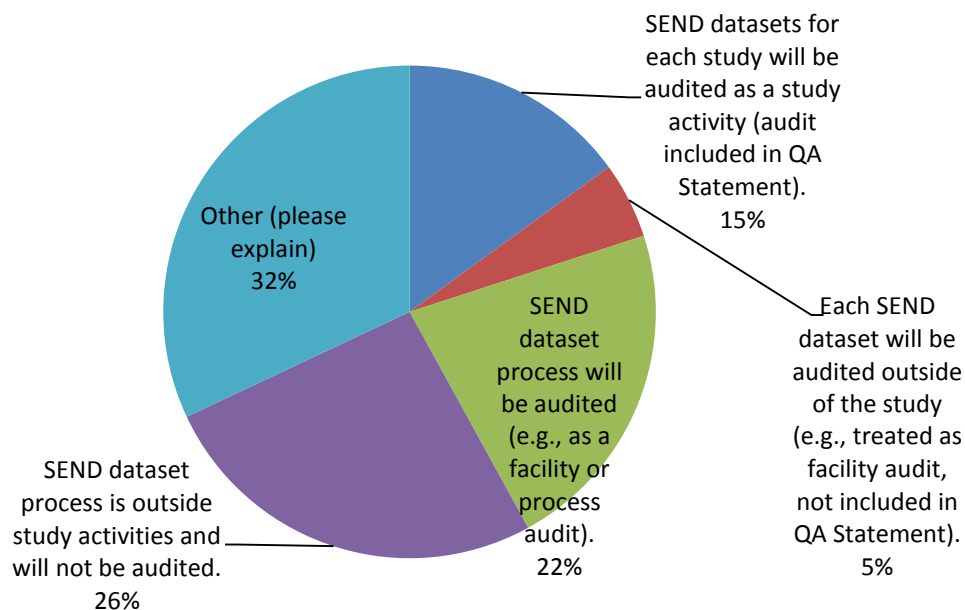
	reconciliation testing before analysis
1	As the SEND dataset will represent the study data, it is important that dataset generation not begin until after the study data are static (i.e., following data audits). Providing the dataset prior to study finalization will allow sponsors to review the dataset and provide any feedback or questions on the data relative to the study prior to issuing the final report.
1	Identify and resolve issues fresh in minds of SMEs in case study is included in future submission.

9. Will SEND datasets be used by the study director to interpret and analyze the data collected and to draw conclusions that are included in the final report?



Value	Percent	Count
Yes	9.9%	11
No	36.9%	41
Certain occasions, when specified in the protocol	9.9%	11
Not sure	43.2%	48
Total		111

10. How will your company provide QA oversight of the SEND dataset process?



Value	Percent	Count
SEND datasets for each study will be audited as a study activity (audit included in QA Statement).	15.3%	17
Each SEND dataset will be audited outside of the study (e.g., treated as facility audit, not included in QA Statement).	5.4%	6
SEND dataset process will be audited (e.g., as a facility or process audit).	21.6%	24
SEND dataset process is outside study activities and will not be audited.	26.1%	29
Other (please explain)	31.5%	35

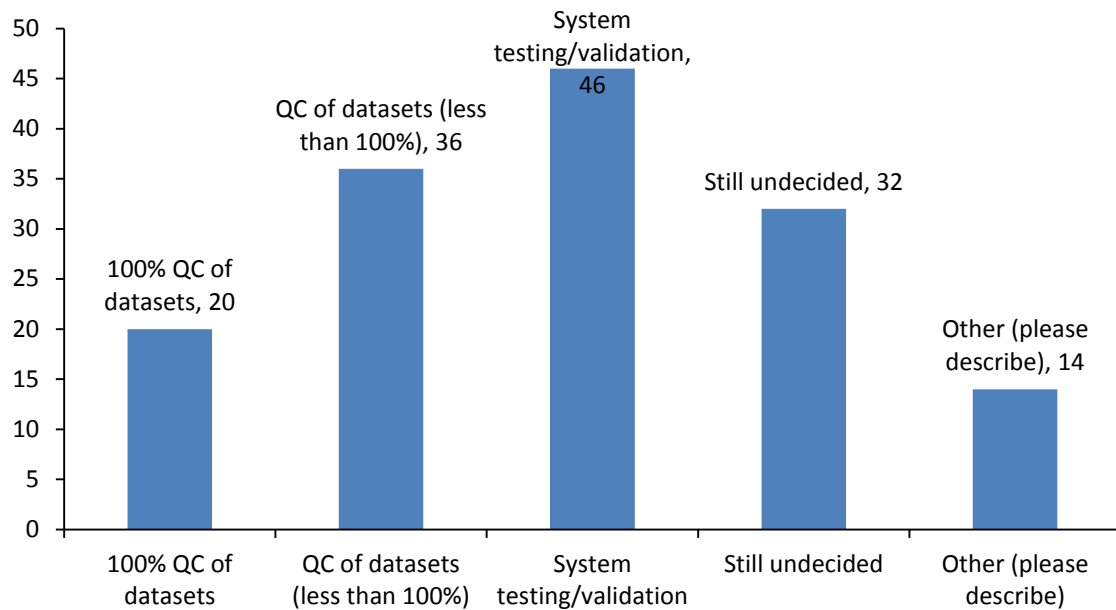
Total		111
Responses"Other (please explain)"		Count
Left Blank		76
Do not know at this time.		1
N/A		1
NA		2
No decided yet		1
None		1
Not considered yet		1
Not decided yet		2
Not sure at this time		1
QA is not expected to audit datasets but will audit the vendor and process.		1
Still determining process		1
Still to be determined.		1
Still undecided		2
Still unsure at what point the QAU will audit the datasets		1
Study Directors should outdit the data.		1

TBD	2
This is confidential	1
Under consideration	1
Unknown at this time.	1
We are a SEND solutions provider with complete set of products and services	1
don't know	1
no SEND data for now	1
not decided yet	1
not sure	2
only validation process	1
to be decided	1
undetermined	1
undetermined at this time	1
unknown for IT	1
As data are used as a regulatory submission---and need to match the GLP final reports, a audit is envisioned. Probably without inclusion on a QA statement, but for each study in some way.	1

Yet to be determined. QA occurs at several levels in the processing of any SEND dataset, Submitted datasets will likely have audit included in QA statement.

1

11. How do you ensure that your datasets completely and accurately represent the study data? (Select all that apply.)



Value	Percent	Count
100% QC of datasets	19.8%	22
QC of datasets (< 100%)	36.0%	40
System testing/validation	46.0%	51
Still undecided	31.5%	35
Other	14.4%	16
Total		111

Statistics

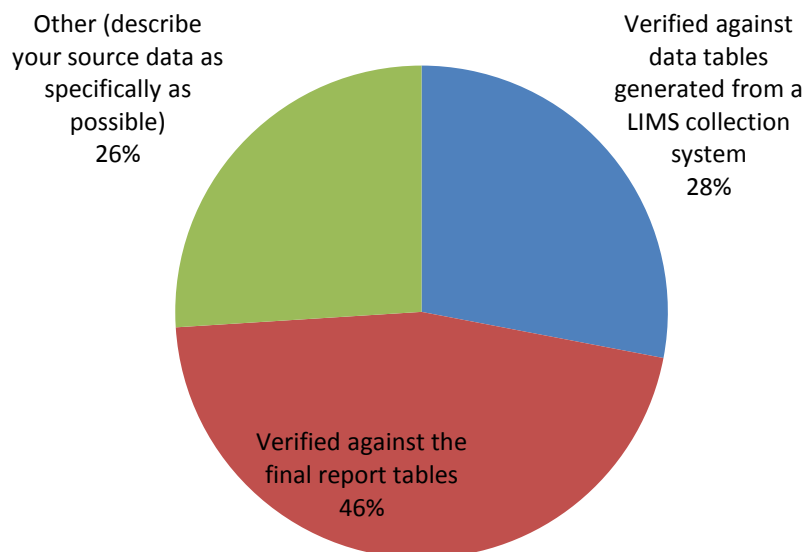
Sum	2,200.0
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Average	19.8
Max	100.0

Responses"Other (please describe)"	Count
Left Blank	95
Do not know at this time.	1
Followed by 30% reviewed by independent QA.	1
NA	1
Part of CRO Service	1
Pivotal study data is summarized from SEND and compared to summary tables in the report.	1
QA spot check	1
TBD	1
Try to avoid manual process which requires 100% QC	1
We will follow guidance from our federal contract leads.	1
along with checks against study plan, schedule and report.	1
no SEND data for now	1

to be decided	1
unknown for IT	1
We will most likely rely on the contract with the service provider. Study director or management may decide to add a QC process if deemed necessary.	1
Presently, we are validating the system we are using to generate our SEND datasets and doing a dry run of dataset submission to SEND Expert so as to see if our data is represented correctly; as for the datasets completeness, we have a team in charge to ensure that the data submitted by the study directors are complete.	1
100% QC of manually entered data ; otherwise system will be validated for data coming from LIMS system.	1

12. What will you use as the reference source to verify (QC) your datasets against?



Value	Percent	Count
Verified against data tables generated from a LIMS collection system	27.9%	31
Verified against the final report tables	46.0%	51
Other (describe your source data as specifically as possible)	26.1%	29
Total		111
Responses"Other (describe your source data as specifically as possible)"		Count
Left Blank		82
Against original raw data		1

Do not know at this time.	1
Machine prints as well as observation recorded in controlled & approved formats.	1
May well depend on the actual CRO we are using	1
NA	1
None	1
Not considered yet	1
QA'ed datasets provided from BA lab	1
Still under discussion	1
TBD	2
Unknown at this time.	1
Verified against manual data forms whee data is not in the LIMS system	1
We will follow guidance from our federal contract leads.	1
along with checks against study plan, schedule and report.	1
don't know	1
n/a	1
no SEND data for now	1

not sure	1
original source data	1
report tables and lims if needed	1
still undecided	1
to be decided	1
unknown for IT	1
verify against report or source data	1
This will be verified against report tables and raw data. Not all of the required SEND items appear on report tables. Therefore it is necessary to go back to raw data.	1
Its our data management team to decide for this matter but it could be both LIMS and final report tables.	1
Generally against the final report tables, from data sources (electronic and non-electronic) for data that is not tabulated in the final report.	1
need to match the raw data and the final report as the accuracy of SEND and final report tables is expected. All should match.	1

13. If applicable, are you ready to...

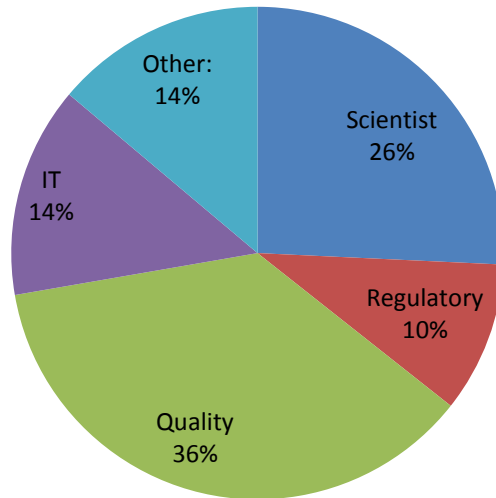
	Yes	No	Partially	Not applicable	Responses
Receive SEND dataset packages	34.3 % 35	17.6 % 18	21.6 % 22	26.5 % 27	102
Review SEND dataset packages	37.9 % 39	26.2 % 27	21.4 % 22	14.6 % 15	103
Analyze SEND dataset packages	18.3 % 19	29.8 % 31	25.0 % 26	26.9 % 28	104
Submit SEND dataset packages	18.9 % 20	29.2 % 31	32.1 % 34	19.8 % 21	106

Thank you for taking the time to complete this survey. If you have any additional remarks you would like to share, please use the space below.

Count	Response
1	Most of my work is with medical devices, and few studies require PK or ADME
1	Nil
1	No
1	No thanks
1	Thanks for this informative survey!
1	We look forward to the results and continued review of SEND topics at SQA in Dallas, etc.
1	What are the timelines for SEND compliance ?
1	<p>FDA should provide a clear expectation for the level of GLP QAU audit expected for SEND data and the method of documentation (QA statement, study audit reports to management/SD etc.) as applicable. If NOT required, this should be explicitly stated.</p> <p>UNTIL THEN---As this data is submitted and used for regulatory decision making, we will assume it must be reviewed and must match final report tables/raw study data.</p>
1	Thank you for keeping us informed as this moves forward and lab determine the best ways to implement and lead us to an industry

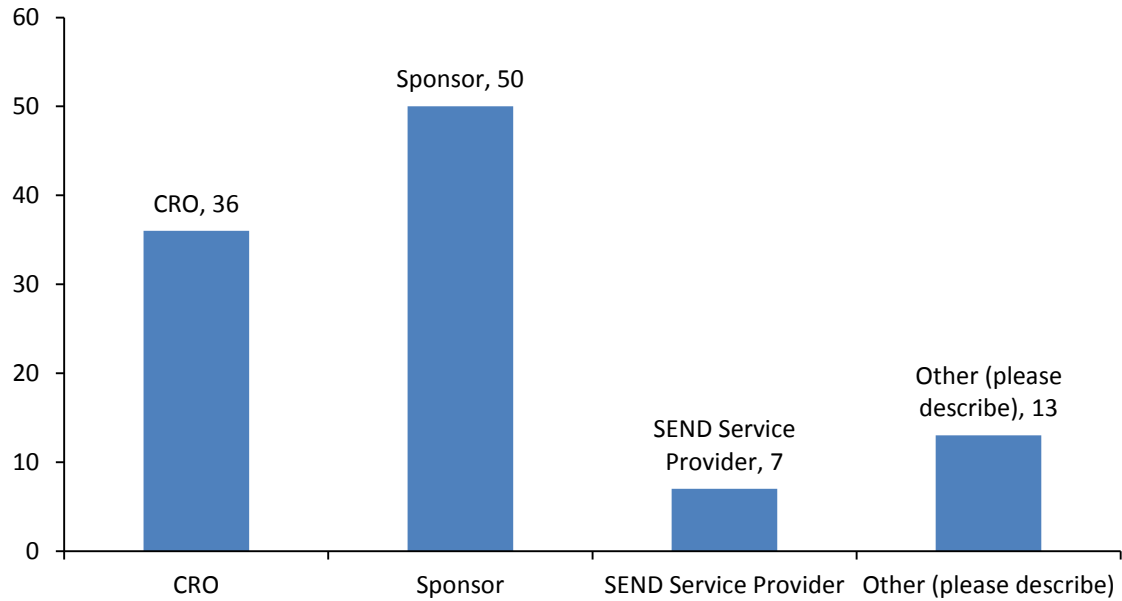
	standard of practice.
1	We've not explored our needs fully at this time, so several answers may not reflect our final analysis.
1	My replies are limited to Consultant QA/QC services but I believe the responses are the best fit for my type of clients, small CRO.
1	1) Is it mandatory to use automation (computer system) for implementation of SEND ? 2) Can we adopt SEND for manual report designing ?
1	PhUSE SEND online info is always appreciated. Please keep reaching out with info necessary. Is Bioanalytical work (eg immunogenicity) need to be in SEND?
1	Not clear what is meant by "analyze SEND dataset" in question 13 and how this differs from reviewing the dataset.

What is your primary job area?



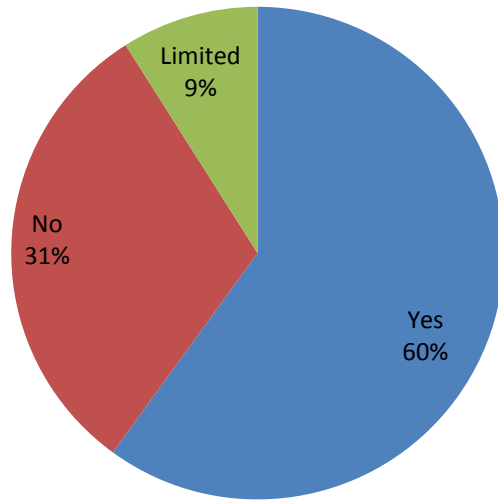
Value	Percent	Count
Scientist	26.1%	29
Regulatory	9.9%	11
Quality	36.9%	41
IT	13.5%	15
Other:	13.5%	15
Total		111

1. Demographic: Is your organization primarily a (select all that apply):



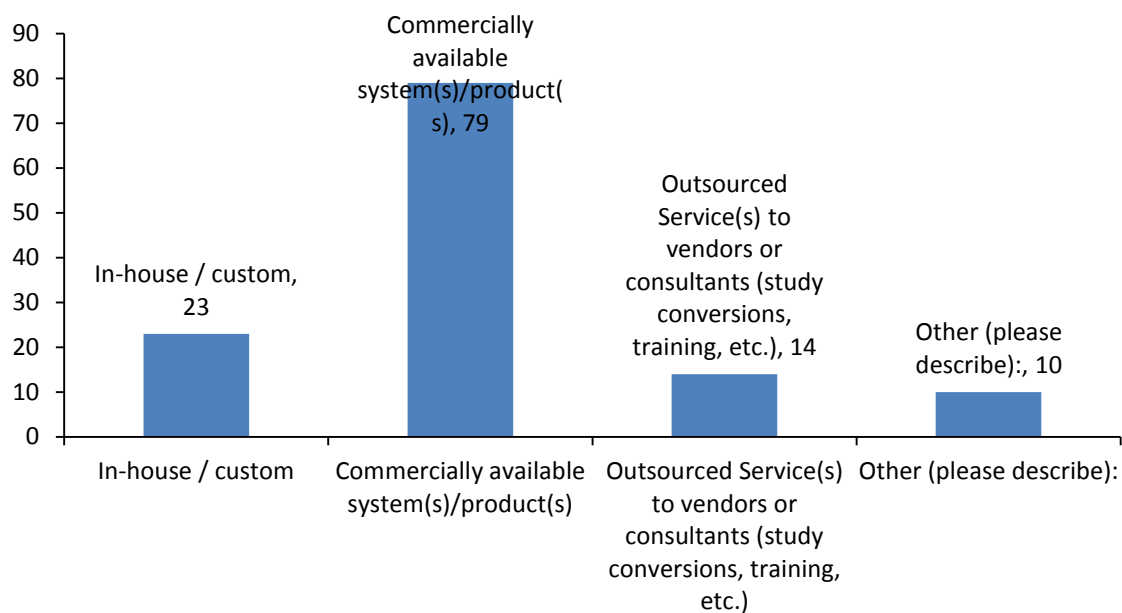
Value	Percent	Count
CRO	36.0%	40
Sponsor	50.5%	56
SEND Service Provider	7.2%	8
Other (please describe)	12.6%	14
Total		111

2. Do you run studies in-house that will be submitted to FDA?



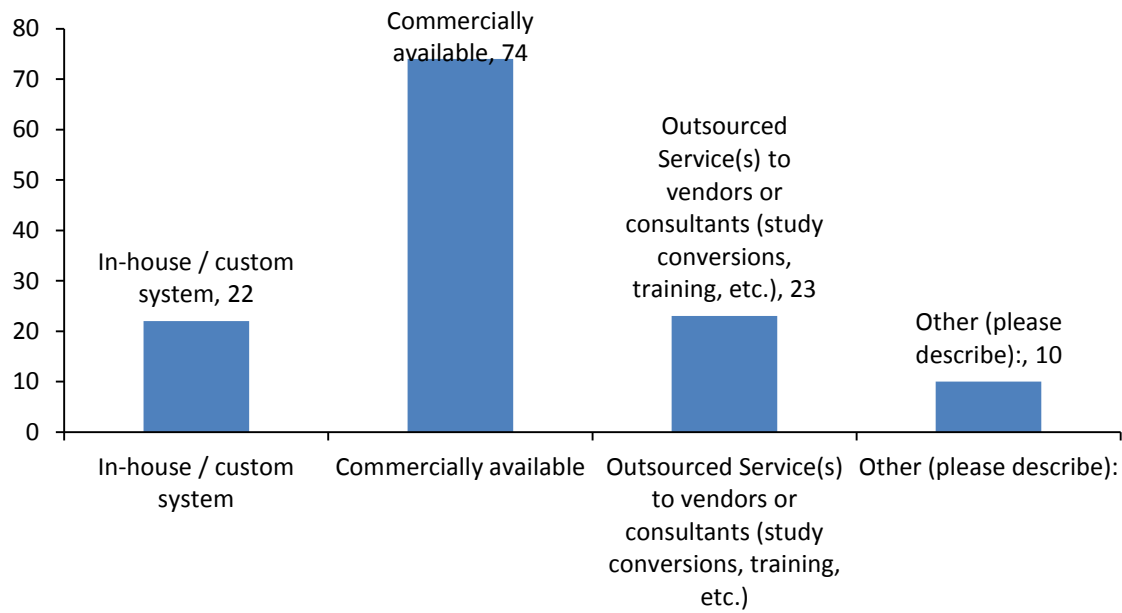
Value	Percent	Count
Yes	60.4%	67
No	30.6%	34
Limited	9.0%	10
Total		111

For Nonclinical Drug Safety/ General Toxicology (select all that apply):



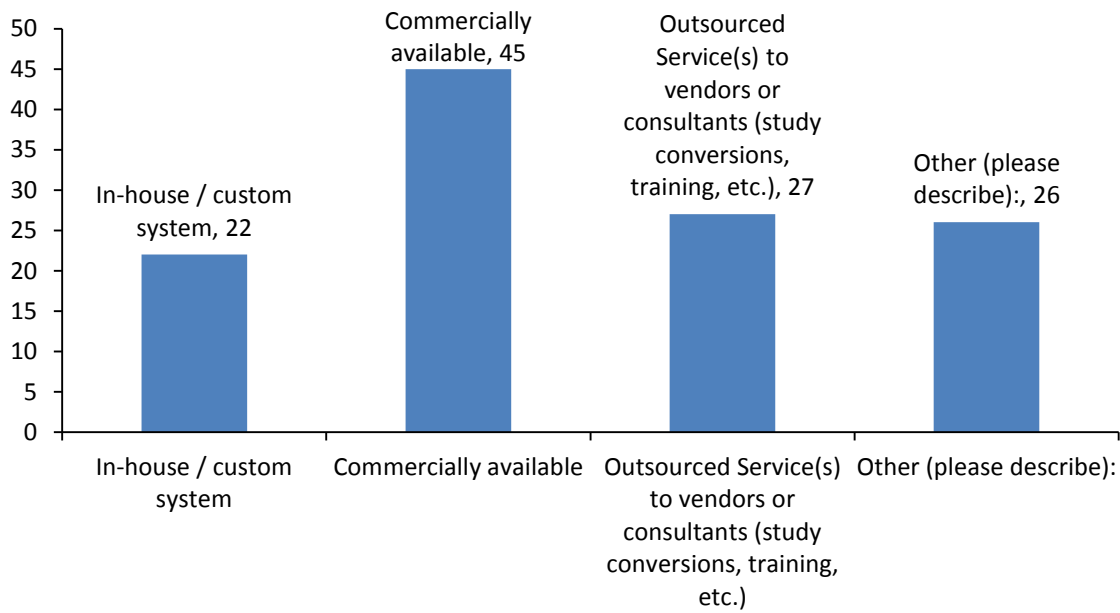
Value	Percent	Count
In-house / custom	23.4%	18
Commercially available system(s)/product(s)	79.2%	61
Outsourced Service(s) to vendors or consultants (study conversions, training, etc.)	14.3%	11
Other (please describe):	10.4%	8
Total		77

For DMPK and Analytical (select all that apply):



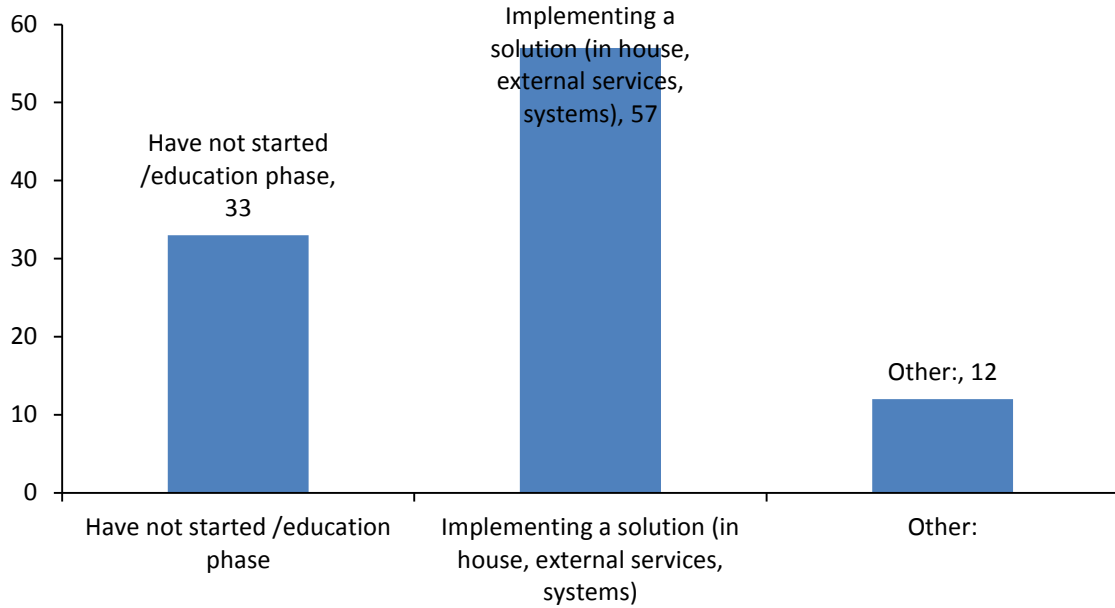
Value	Percent	Count
In-house / custom system	22.1%	17
Commercially available	74.0%	57
Outsourced Service(s) to vendors or consultants (study conversions, training, etc.)	23.4%	18
Other (please describe):	10.4%	8
Total		77

For Repro/DART (select all that apply):



Value	Percent	Count
In-house / custom system	22.1%	17
Commercially available	45.5%	35
Outsourced Service(s) to vendors or consultants (study conversions, training, etc.)	27.3%	21
Other (please describe):	26.0%	20
Total		77

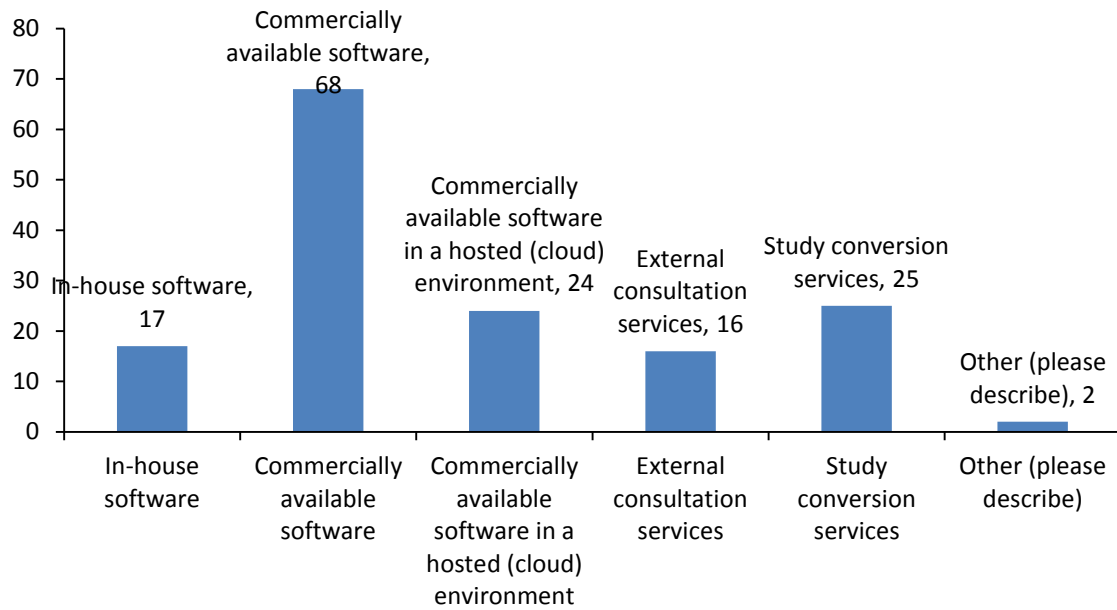
3. What stage of SEND readiness are you in? (select all that are appropriate)



Value	Percent	Count
Have not started /education phase	33.3%	37
Implementing a solution (in house, external services, systems)	56.8%	63
Other:	11.7%	13
Total		111

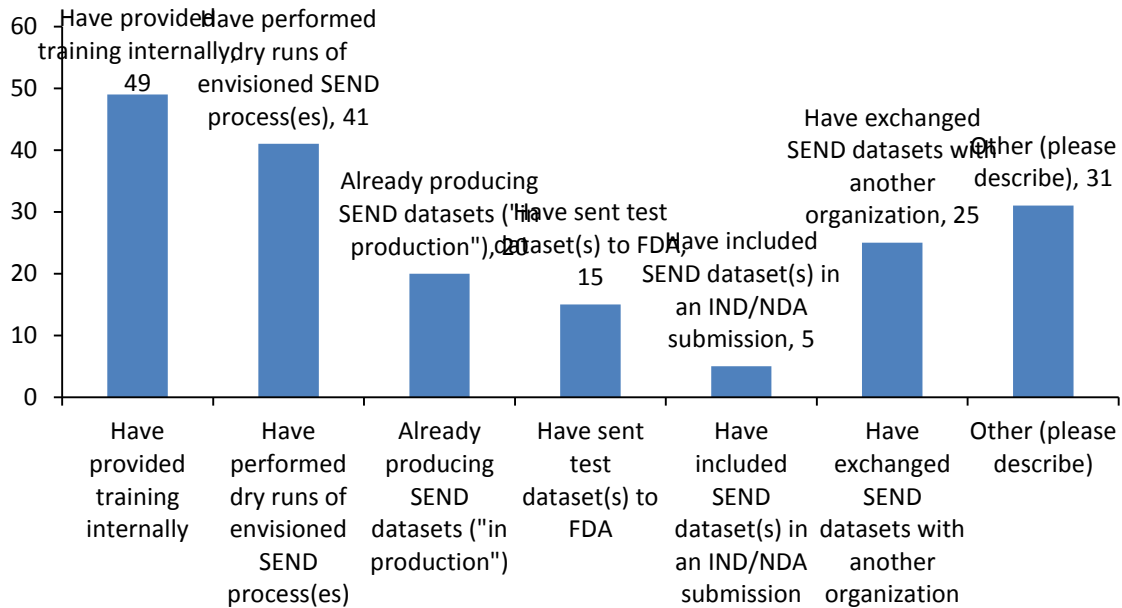
Please tell us about the system(s) you are implementing

(select all that apply):



Value	Percent	Count
In-house software	17.5%	11
Commercially available software	68.3%	43
Commercially available software in a hosted (cloud) environment	23.8%	15
External consultation services	15.9%	10
Study conversion services	25.4%	16
Other (please describe)	1.6%	1
Total		63

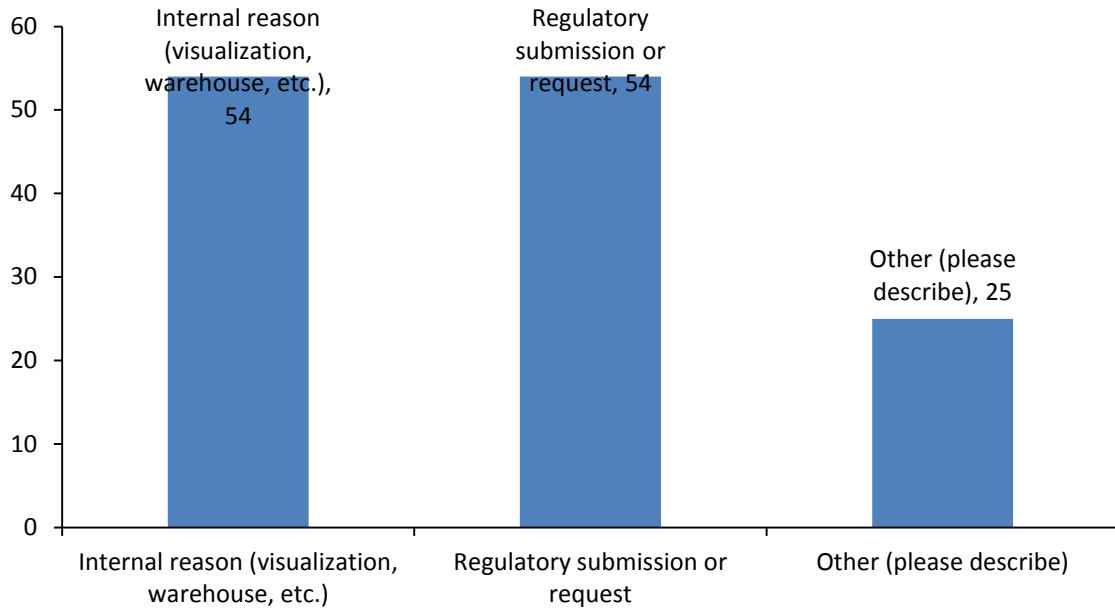
4. What actions are you currently taking / have taken towards implementation? (select all that apply)



Value	Percent	Count
Have provided training internally	48.7%	54
Have performed dry runs of envisioned SEND process(es)	40.5%	45
Already producing SEND datasets ("in production")	19.8%	22
Have sent test dataset(s) to FDA	15.3%	17
Have included SEND dataset(s) in an IND/NDA submission	4.5%	5
Have exchanged SEND datasets with another organization	25.2%	28

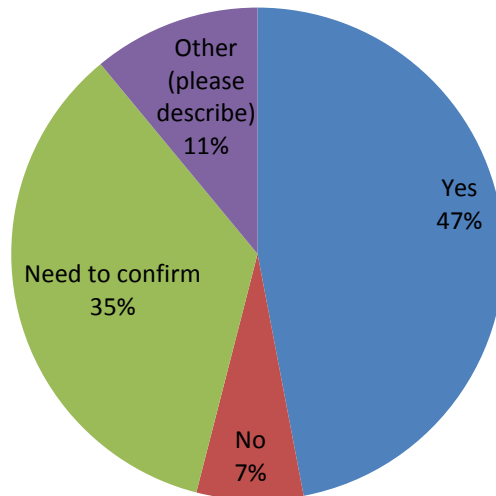
Other (please describe)	30.6%	34
Total		111

What was the purpose of the dataset exchange? (select all that apply)



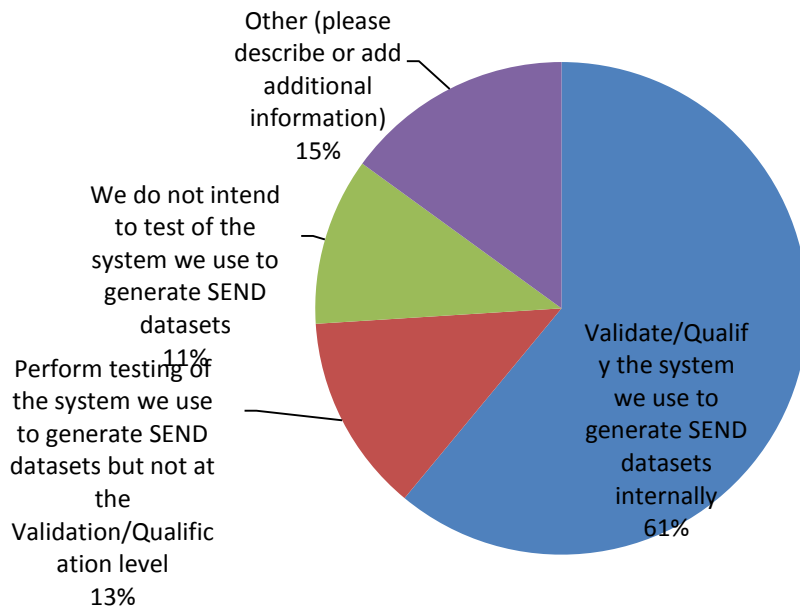
Value	Percent	Count
Internal reason (visualization, warehouse, etc.)	53.6%	15
Regulatory submission or request	53.6%	15
Other (please describe)	25.0%	7
Total		28

5. Are your service providers able to create SEND datasets or have a plan in place to do this in the right timeframe?



Value	Percent	Count
Yes	46.9%	52
No	7.2%	8
Need to confirm	35.1%	39
Other (please describe)	10.8%	12
Total		111

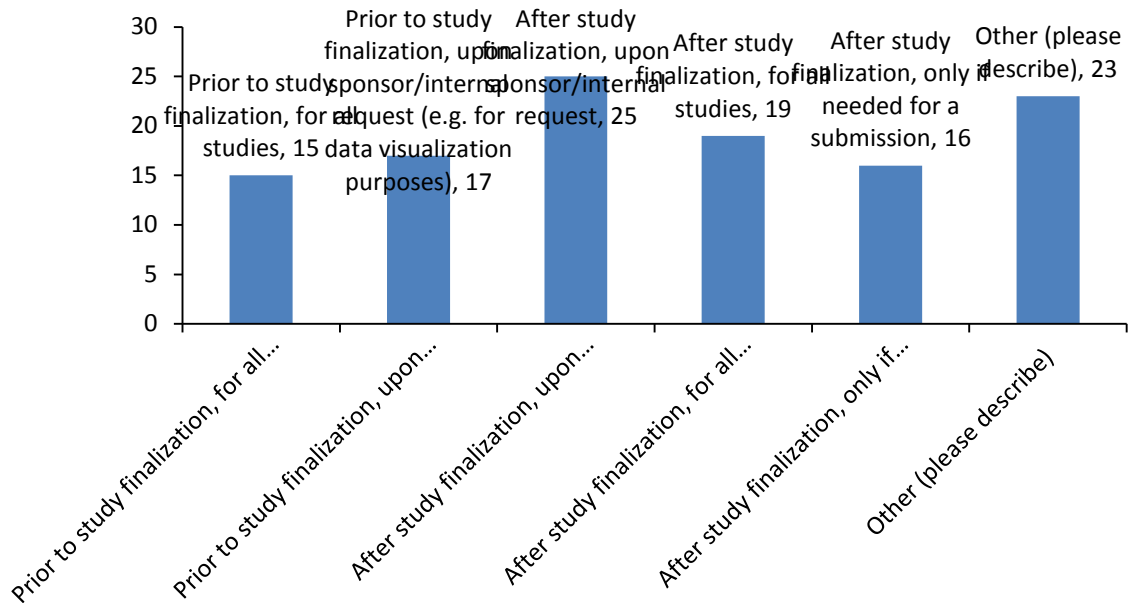
6. With regard to your company's implementation of a SEND computer system(s), at what level do you intend to test the system?



Value	Percent	Count
Validate/Qualify the system we use to generate SEND datasets internally	61.3%	68
Perform testing of the system we use to generate SEND datasets but not at the Validation/Qualification level	12.6%	14
We do not intend to test of the system we use to generate SEND datasets	10.8%	12
Other (please describe or add additional information)	15.3%	17

Total		111
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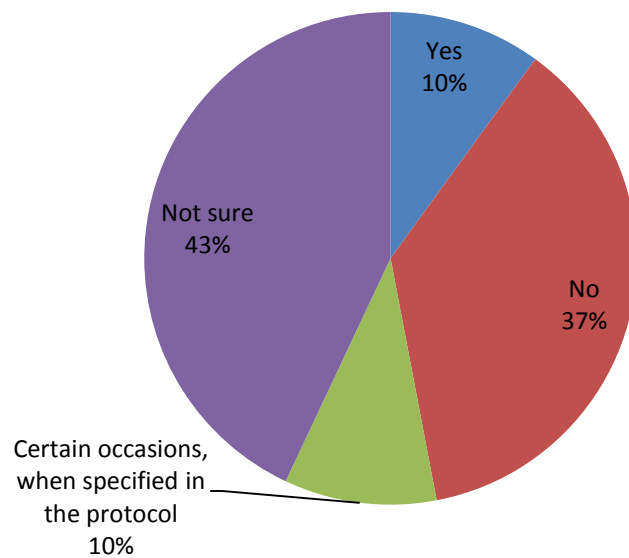
7. At what point related to study finalization (report signed by Study Director) does your company plan to generate SEND datasets? (select all that apply)



Value	Percent	Count
Prior to study finalization, for all studies	15.3%	17
Prior to study finalization, upon sponsor/internal request (e.g. for data visualization purposes)	17.1%	19
After study finalization, upon sponsor/internal request	25.2%	28
After study finalization, for all studies	18.9%	21
After study finalization, only if needed for a submission	16.2%	18

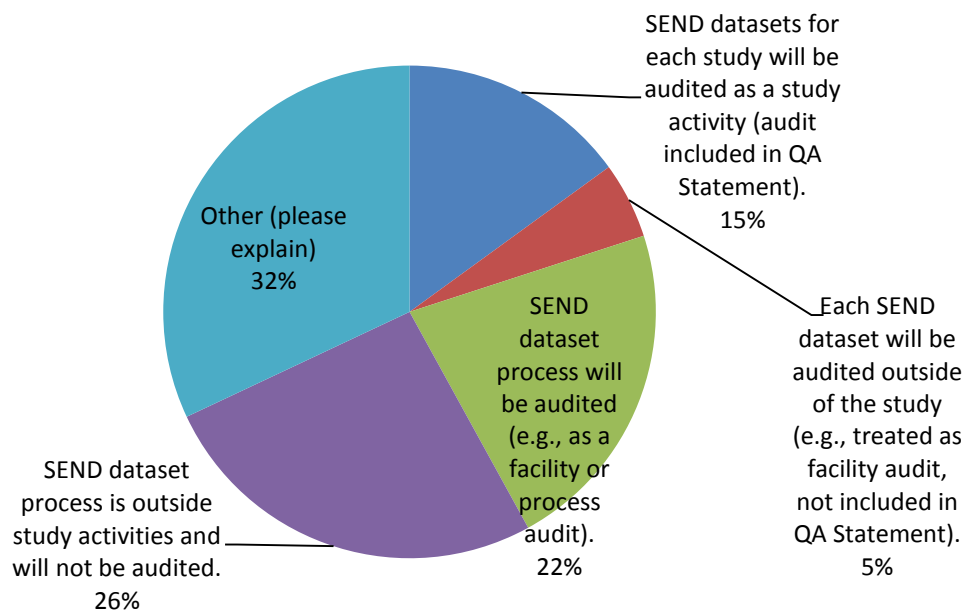
Other (please describe)	22.5%	25
Total		111

9. Will SEND datasets be used by the study director to interpret and analyze the data collected and to draw conclusions that are included in the final report?



Value	Percent	Count
Yes	9.9%	11
No	36.9%	41
Certain occasions, when specified in the protocol	9.9%	11
Not sure	43.2%	48
Total		111

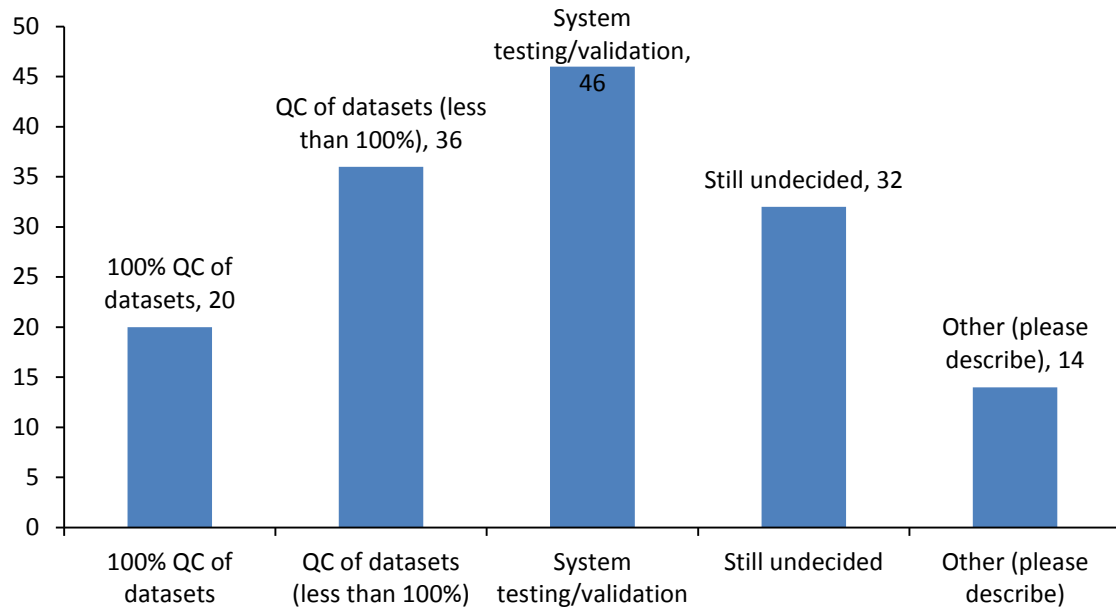
10. How will your company provide QA oversight of the SEND dataset process?



Value	Percent	Count
SEND datasets for each study will be audited as a study activity (audit included in QA Statement).	15.3%	17
Each SEND dataset will be audited outside of the study (e.g., treated as facility audit, not included in QA Statement).	5.4%	6
SEND dataset process will be audited (e.g., as a facility or process audit).	21.6%	24
SEND dataset process is outside study activities and will not be audited.	26.1%	29
Other (please explain)	31.5%	35

Total		111
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11. How do you ensure that your datasets completely and accurately represent the study data? (Select all that apply.)



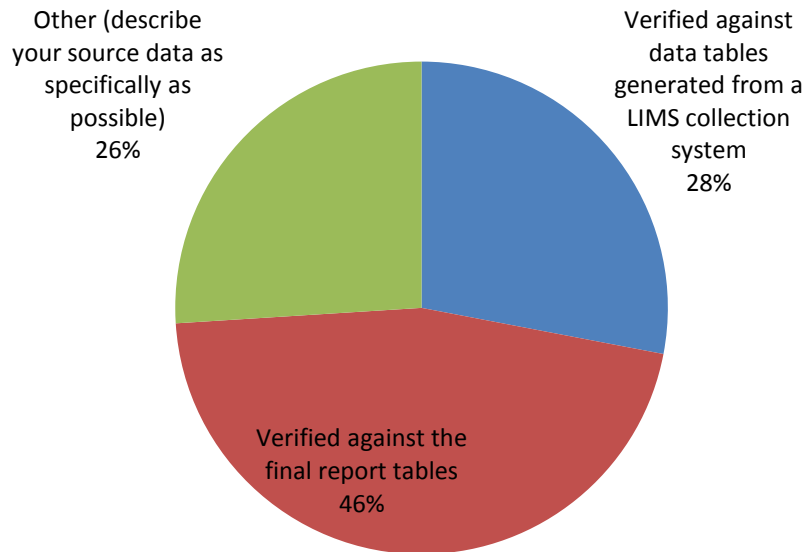
Value	Percent	Count
100% QC of datasets	19.8%	22
QC of datasets (less than 100%)	36.0%	40
System testing/validation	46.0%	51
Still undecided	31.5%	35
Other (please describe)	14.4%	16
Total		111

Statistics

Sum	2,200.0
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Average	19.8
Max	100.0

12. What will you use as the reference source to verify (QC) your datasets against?

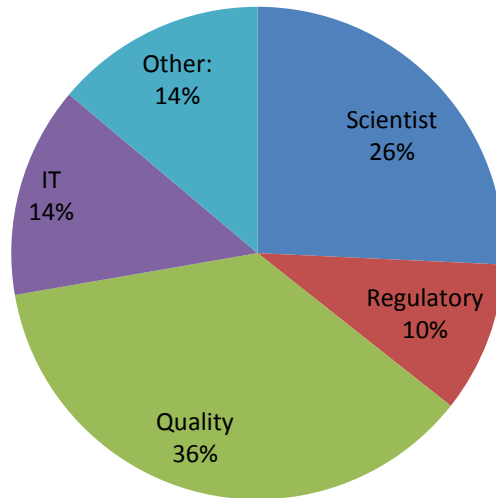


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13. If applicable, are you ready to...

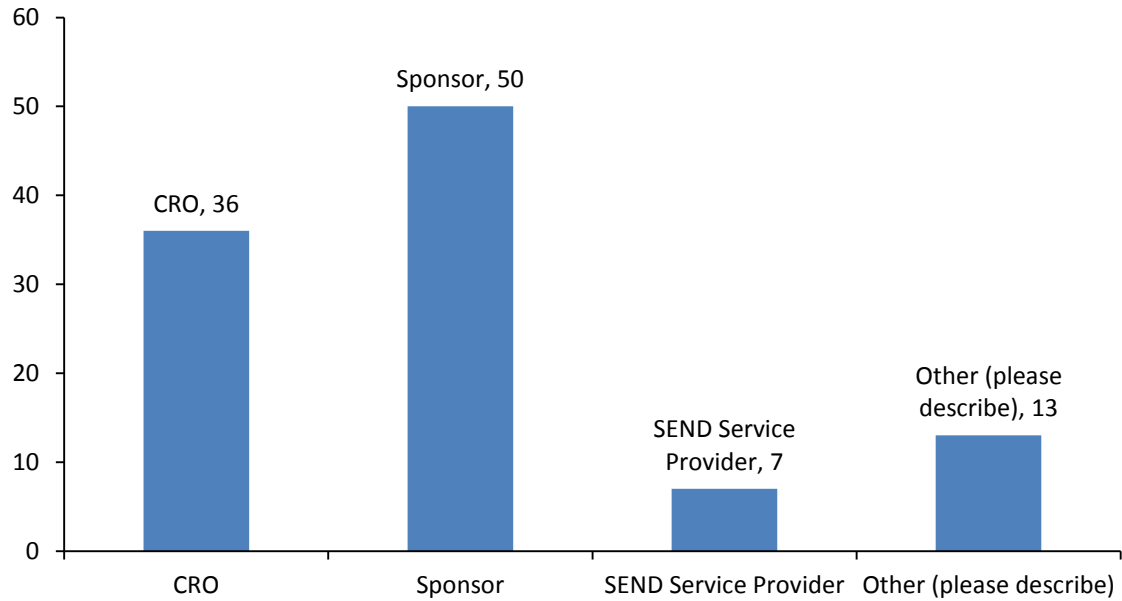
	Yes	No	Partially	Not applicable	Responses
Receive SEND dataset packages	34.3 % 35	17.6 % 18	21.6 % 22	26.5 % 27	102
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Analyze SEND dataset packages	18.3 % 19	29.8 % 31	25.0 % 26	26.9 % 28	104
Submit SEND dataset packages	18.9 % 20	29.2 % 31	32.1 % 34	19.8 % 21	106

What is your primary job area?



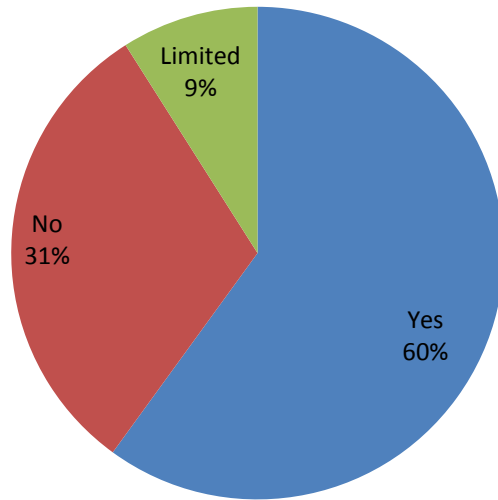
Value	Percent	Count
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Quality	36.9%	41
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Total		111

1. Demographic: Is your organization primarily a (select all that apply):



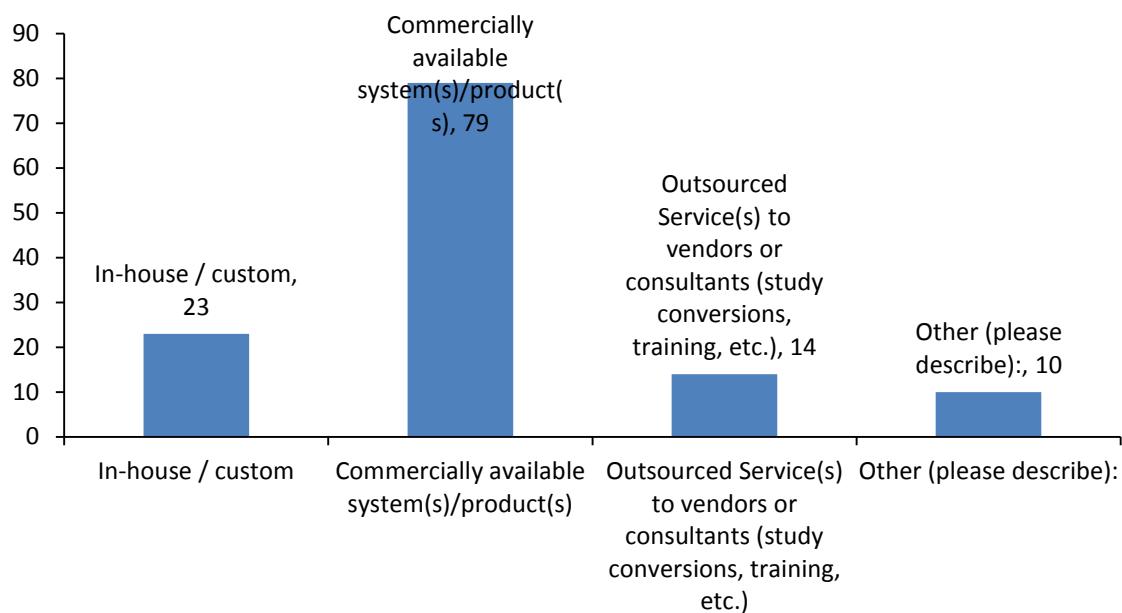
Value	Percent	Count
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Sponsor	50.5%	56
SEND Service Provider	7.2%	8
Other (please describe)	12.6%	14
Total		111

2. Do you run studies in-house that will be submitted to FDA?



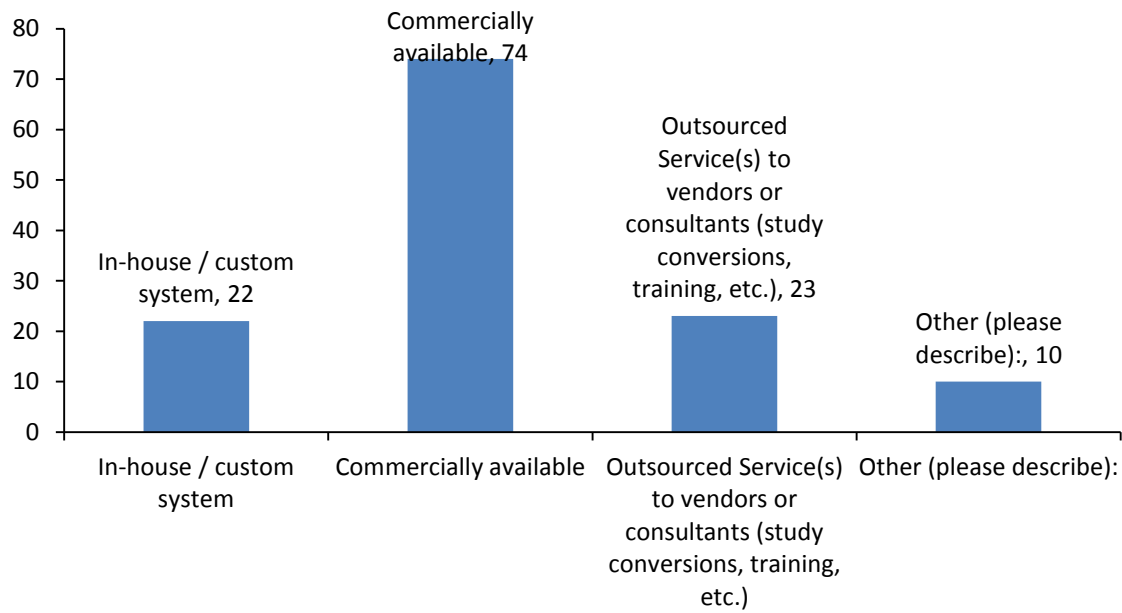
Value	Percent	Count
Yes	60.4%	67
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Limited	9.0%	10
Total		111

For Nonclinical Drug Safety/ General Toxicology (select all that apply):



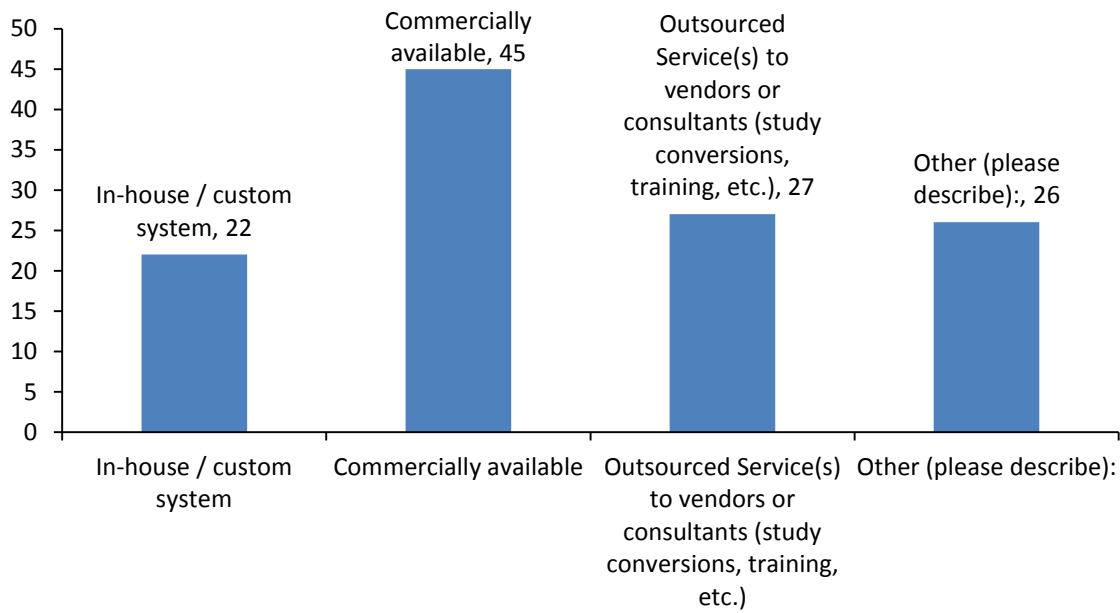
Value	Percent	Count
In-house / custom	23.4%	18
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Outsourced Service(s) to vendors or consultants (study conversions, training, etc.)	14.3%	11
Other (please describe):	10.4%	8
Total		77

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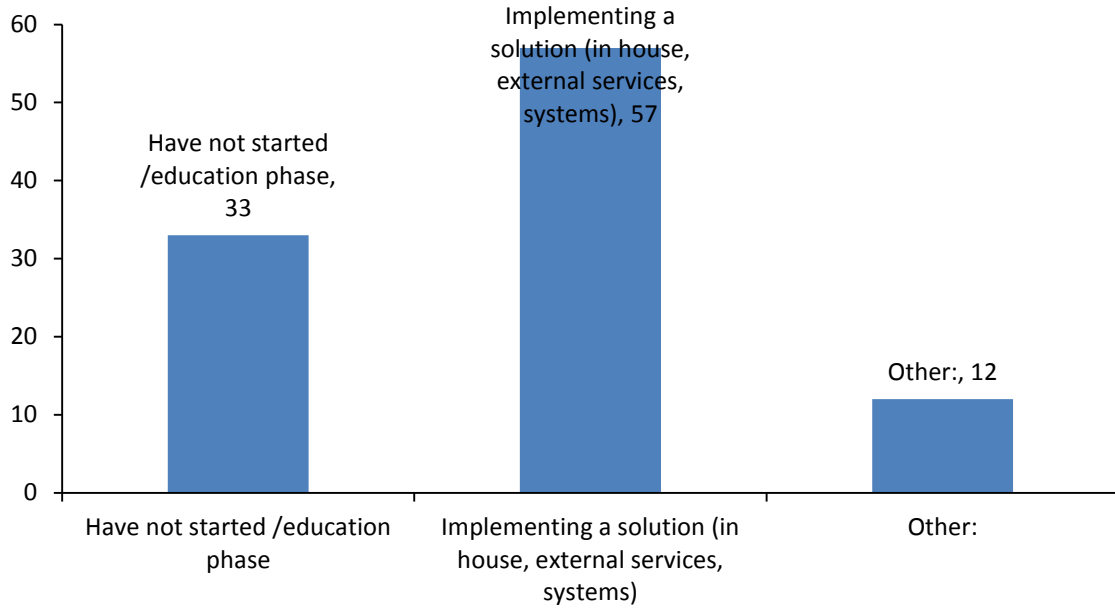
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For Repro/DART (select all that apply):



Value	Percent	Count
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Commercially available	45.5%	35
Outsourced Service(s) to vendors or consultants (study conversions, training, etc.)	27.3%	21
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Total		77

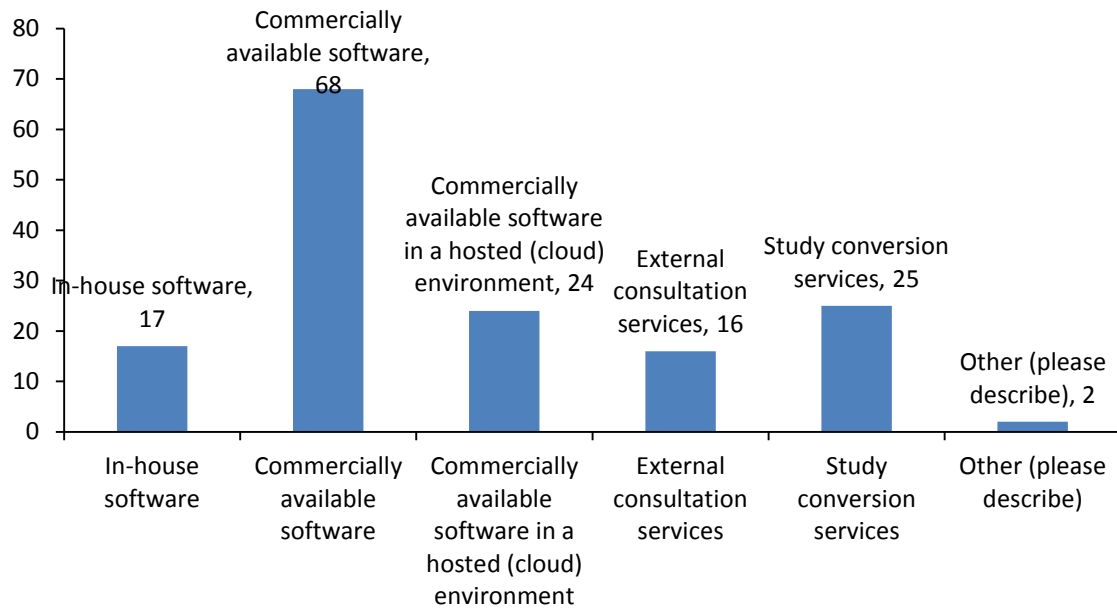
3. What stage of SEND readiness are you in? (select all that are appropriate)



Value	Percent	Count
Have not started /education phase	33.3%	37
Implementing a solution (in house, external services, systems)	56.8%	63
Other:	11.7%	13
Total		111

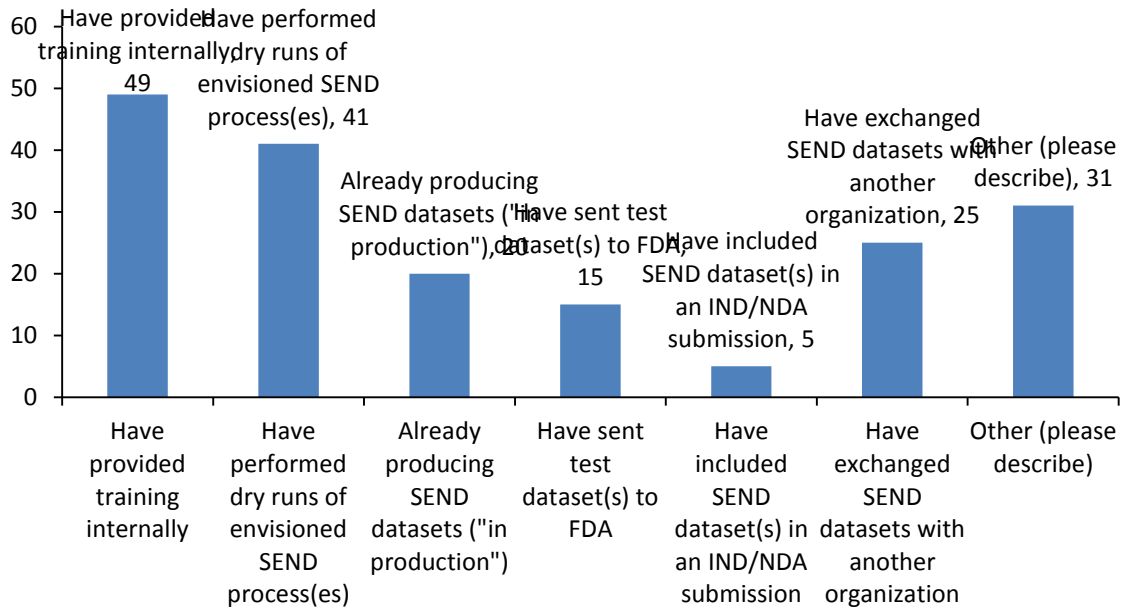
Please tell us about the system(s) you are implementing

(select all that apply):



Value	Percent	Count
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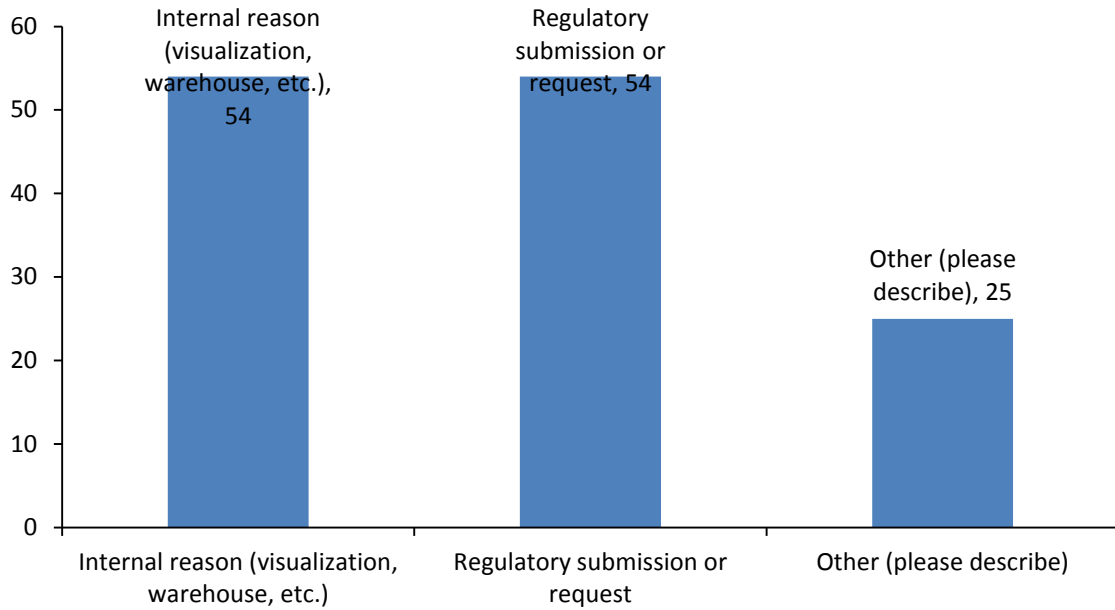
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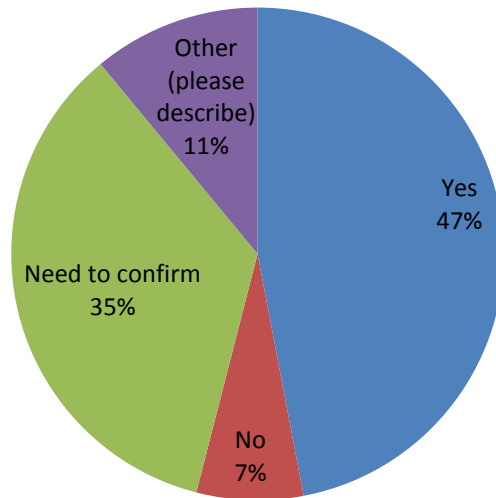
Other (please describe)	30.6%	34
Total		111

What was the purpose of the dataset exchange? (select all that apply)



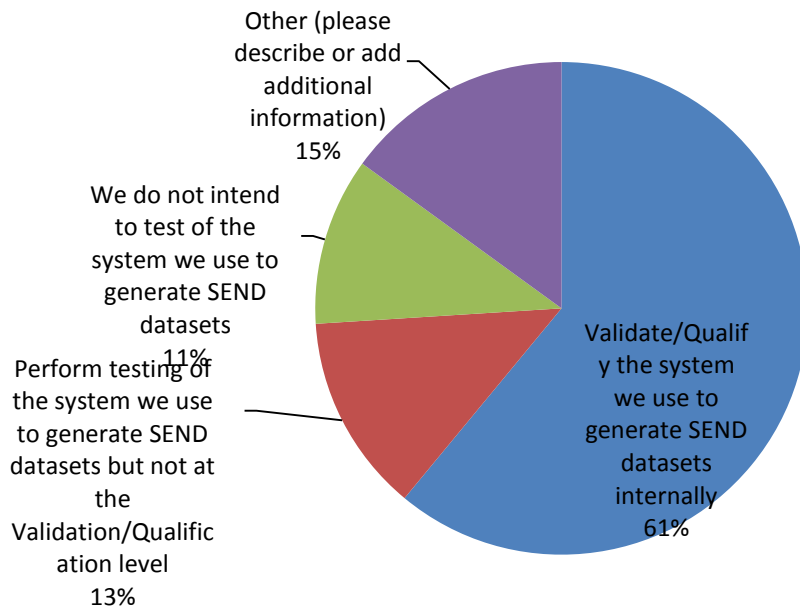
Value	Percent	Count
Internal reason (visualization, warehouse, etc.)	53.6%	15
Regulatory submission or request	53.6%	15
Other (please describe)	25.0%	7
Total		28

5. Are your service providers able to create SEND datasets or have a plan in place to do this in the right timeframe?



Value	Percent	Count
Yes	46.9%	52
No	7.2%	8
Need to confirm	35.1%	39
Other (please describe)	10.8%	12
Total		111

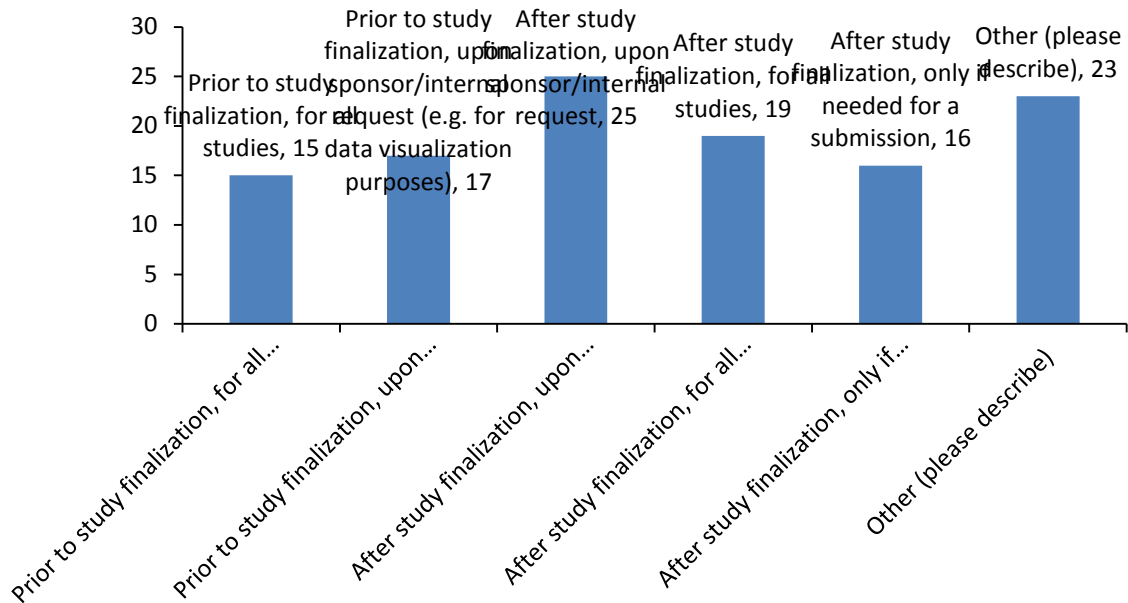
6. With regard to your company's implementation of a SEND computer system(s), at what level do you intend to test the system?



Value	Percent	Count
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We do not intend to test of the system we use to generate SEND datasets	10.8%	12
Other (please describe or add additional information)	15.3%	17

Total		111
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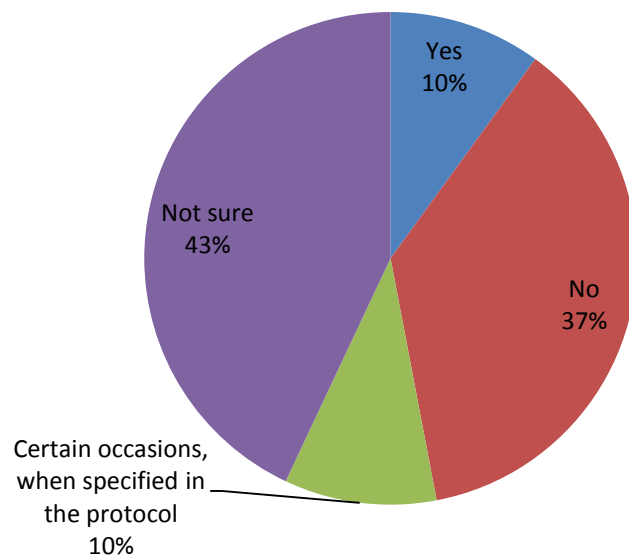
7. At what point related to study finalization (report signed by Study Director) does your company plan to generate SEND datasets? (select all that apply)



Value	Percent	Count
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Prior to study finalization, upon sponsor/internal request (e.g. for data visualization purposes)	17.1%	19
After study finalization, upon sponsor/internal request	25.2%	28
After study finalization, for all studies	18.9%	21
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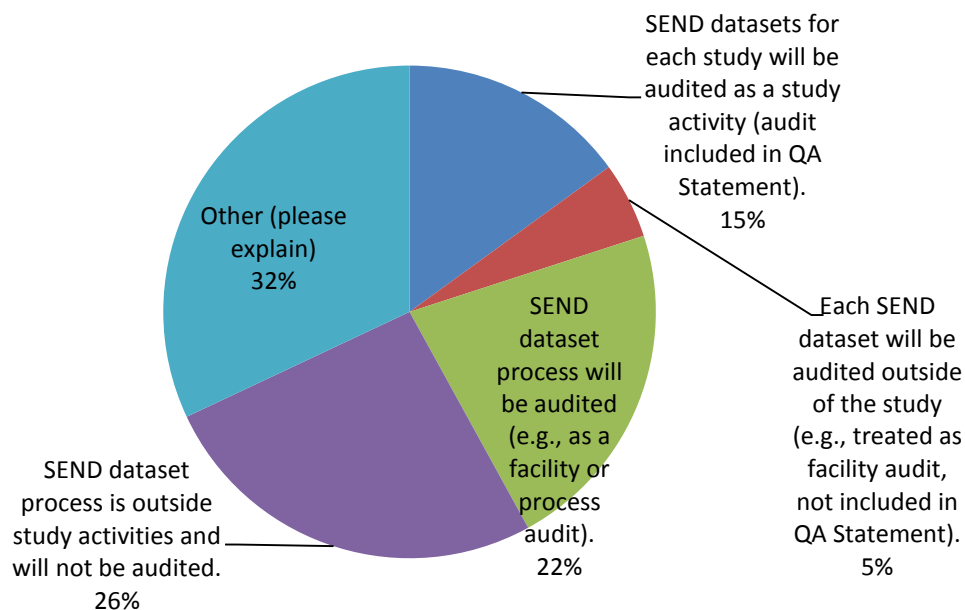
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Total		111

9. Will SEND datasets be used by the study director to interpret and analyze the data collected and to draw conclusions that are included in the final report?



Value	Percent	Count
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No	36.9%	41
Certain occasions, when specified in the protocol	9.9%	11
Not sure	43.2%	48
Total		111

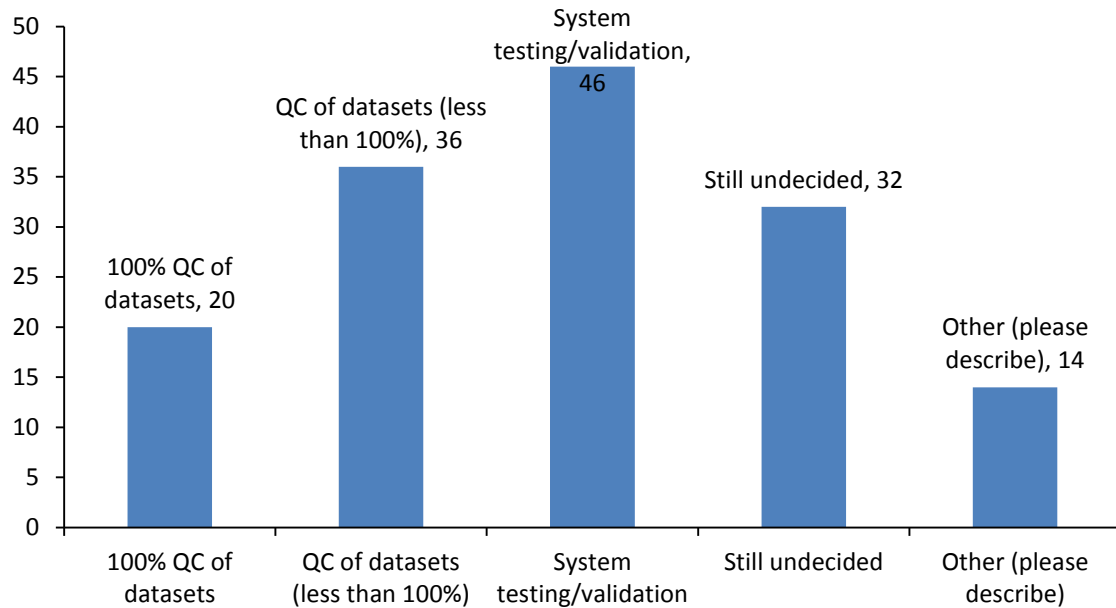
10. How will your company provide QA oversight of the SEND dataset process?



Value	Percent	Count
SEND datasets for each study will be audited as a study activity (audit included in QA Statement).	15.3%	17
Each SEND dataset will be audited outside of the study (e.g., treated as facility audit, not included in QA Statement).	5.4%	6
SEND dataset process will be audited (e.g., as a facility or process audit).	21.6%	24
SEND dataset process is outside study activities and will not be audited.	26.1%	29
Other (please explain)	31.5%	35

Total		111
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11. How do you ensure that your datasets completely and accurately represent the study data? (Select all that apply.)



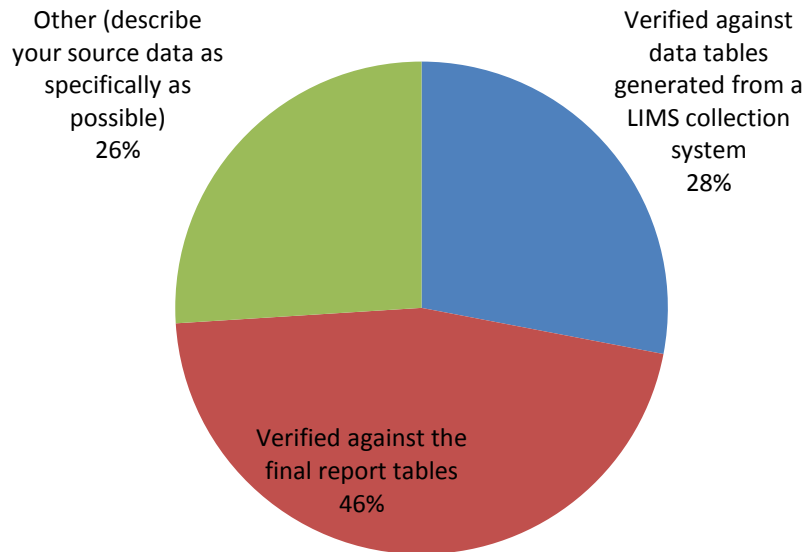
Value	Percent	Count
100% QC of datasets	19.8%	22
QC of datasets (less than 100%)	36.0%	40
System testing/validation	46.0%	51
Still undecided	31.5%	35
Other (please describe)	14.4%	16
Total		111

Statistics

Sum	2,200.0
-----	---------

Average	19.8
Max	100.0

12. What will you use as the reference source to verify (QC) your datasets against?



Value	Percent	Count
Verified against data tables generated from a LIMS collection system	27.9%	31
Verified against the final report tables	46.0%	51
Other (describe your source data as specifically as possible)	26.1%	29
Total		111

13. If applicable, are you ready to...

	Yes	No	Partially	Not applicable	Responses
Receive SEND dataset packages	34.3 % 35	17.6 % 18	21.6 % 22	26.5 % 27	102
Review SEND dataset packages	37.9 % 39	26.2 % 27	21.4 % 22	14.6 % 15	103
Analyze SEND dataset packages	18.3 % 19	29.8 % 31	25.0 % 26	26.9 % 28	104
Submit SEND dataset packages	18.9 % 20	29.2 % 31	32.1 % 34	19.8 % 21	106