EFSPI Statistical Leaders Meeting 2023

Pre-meeting survey by Core Planning Team

Analyses by Armin Schüler and Pascal Kieslich

2023-05-17

Notes on using this document

Browser

Please open this HTML document in any modern web browser. Do **not** open it directly within Microsoft Teams or SharePoint as in this case the interactive tables are not displayed properly.

Single and multliple choice questions

For all single and multiple choice questions the following statistics are provided

- `N` : Number of participants that selected a specific option
- `Percent of all` : Percent of all participants (that completed the survey) that selected this option
- `Percent of responders` : Percent of all responders (i.e., participants that answered this particular question in the survey, which is defined as selecting at least one of the options of the question) that selected this option

Most questions in the survey were multiple choice items. This means that more than one option in a question could be selected (so the percentages typically sum to more than 100%).

The order of the question options corresponds to the original order in the survey.

Other categories

Many questions in the survey contained an “Other” option with an open text field. The specific answers to this option are reported in a separate table for the respective question.

Key words and interactive tables

Several questions in the survey asked participants to name up to three key words. For these questions, both the raw answers and the cleaned answers are provided. The raw answers are provided as one line per participant (lines without any response are removed). The cleaned answers are based on some automatic preprocessing (e.g., removing all text in brackets); in addition, similar answers were grouped together according to our subjective judgment based on a quick screening of the answers (feel free to send us further suggestions for grouping answers).

The tables for the key words are interactive tables that can be searched by entering text in the open text input field above the table. These tables can also be exported by clicking on the corresponding button (e.g., “CSV” or “Excel”) above the table.

Free text

Several items in the survey asked participants to enter free text. For these questions, interactive tables are provided as well.

Word clouds

While the size of a word in the word cloud corresponds to its relative frequency, the position of a word is randomly determined. The seed for reproducing the current word clouds is 495711.

Number of respondents

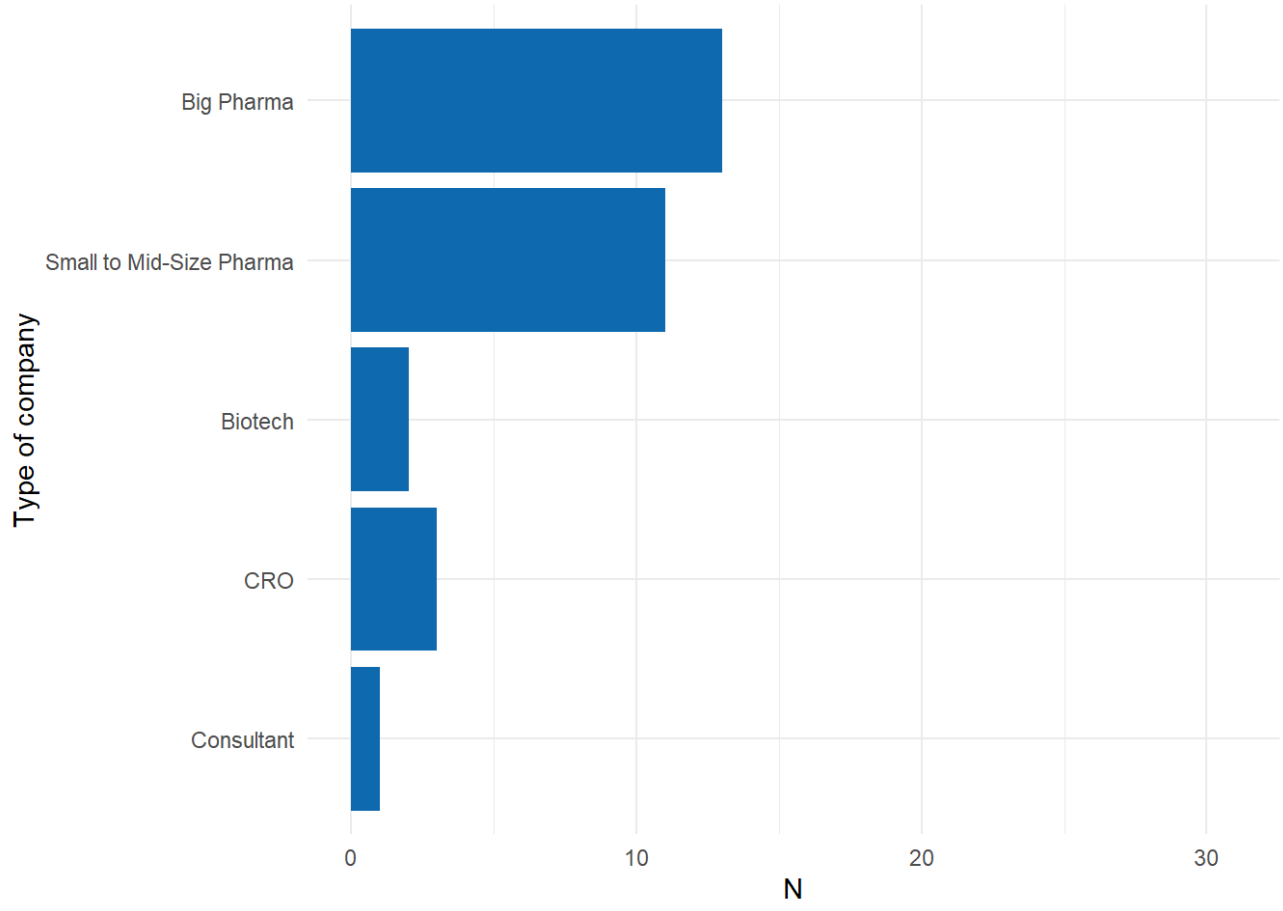
In total, there are 40 questionnaires in which a participant provided answers to at least one of the questions in the survey. However, only 31 participants completed the questionnaire (which in the table below corresponds to arriving at page 6 of the questionnaire). Only data from these 31 participants will be analysed in the following (and subsequently is used as the basis in `Percent of all`).

Last answered page in questionnaire	N	Percent
2	5	12.5
3	2	5.0
4	2	5.0
6	31	77.5

Demographics

Type of company

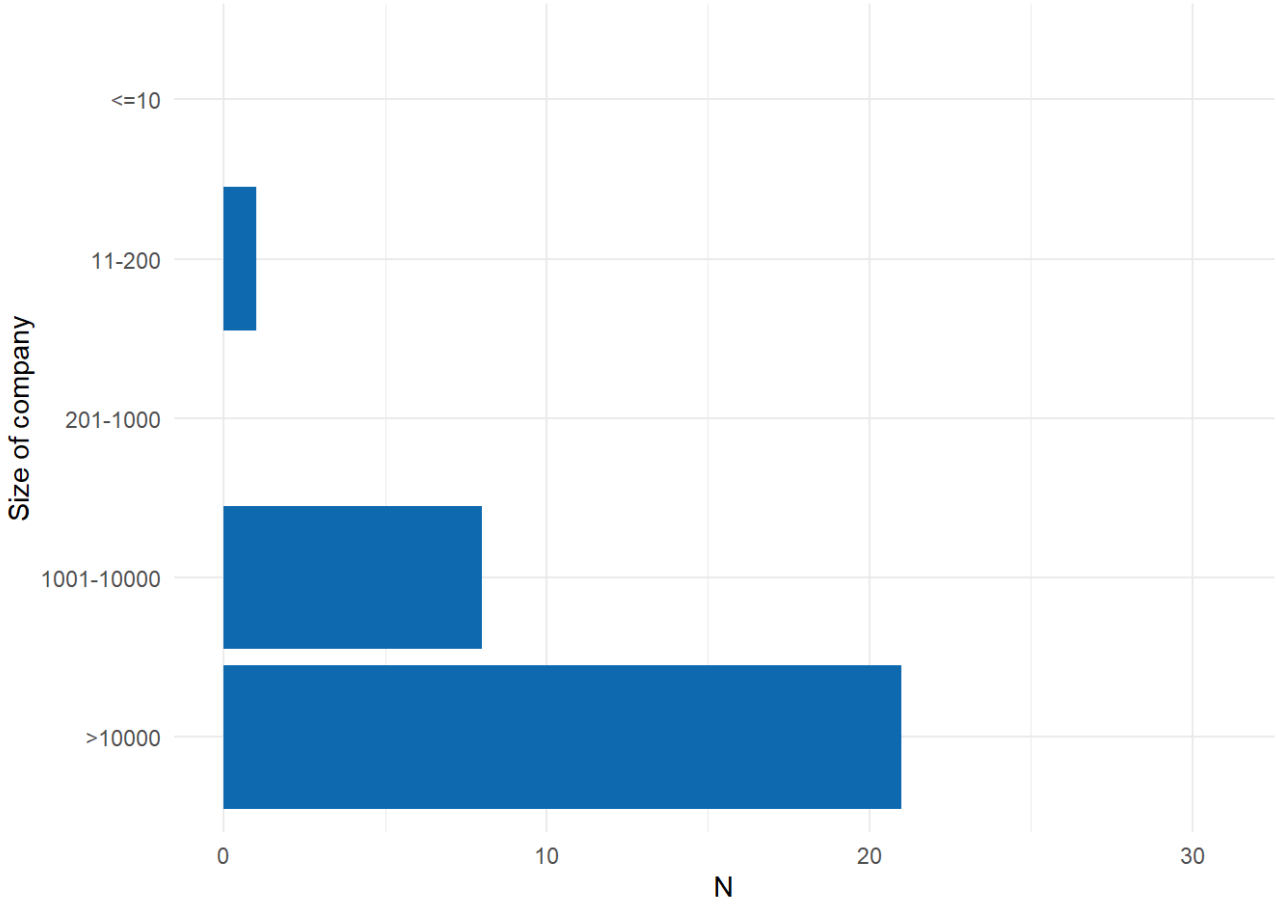
Category	N	Percent of all	Percent of responders
Big Pharma	13	41.9	43.3
Small to Mid-Size Pharma	11	35.5	36.7
Biotech	2	6.5	6.7
CRO	3	9.7	10.0
Consultant	1	3.2	3.3
NA	1	3.2	NA



Size of company

Category	N	Percent of all	Percent of responders
<=10	0	0.0	0.0
11-200	1	3.2	3.3

Category	N	Percent of all	Percent of responders
201-1000	0	0.0	0.0
1001-10000	8	25.8	26.7
>10000	21	67.7	70.0
NA	1	3.2	NA



Name of organization

Answer	N
Biostatistics	5
Analytics	1
Biometrics	1
Biometrics and Data Center	1
Biosimilar Biostatistics	1
Biostatisical Sciences	1
Biostatistics & Data Science	1

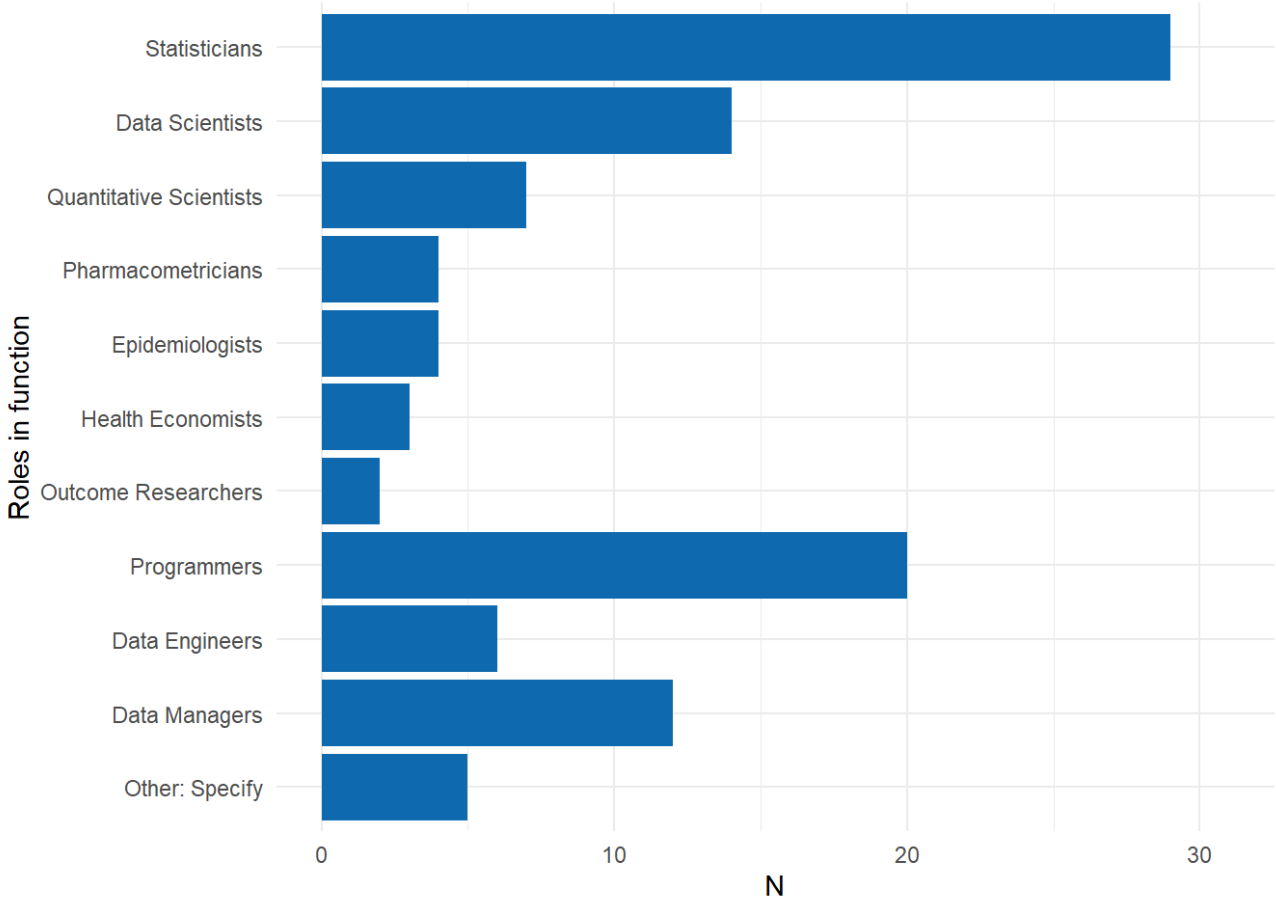
Answer	N
Biostatistics & Programming	1
Biostats & Programming	1
Clinical Data Sciences and Analytics	1
Clinical Operations and Data Science	1
Cytel	1
Evidence Generation	1
Global Biometrics and Data Management	1
Global Biostatistics and Clinical Data Sciences	1
Global Data Operations	1
Global Statistical Sciences	1
Global Statistics and Data Sciences	1
HTA Statistics	1
Oncology Statistics and Data Management	1
Statistical Innovation	1
Statistical Science and Innovation	1
Statistical and Real World Data Science	1
Statistics and Data Management	1
Statistics and Decision Sciences	1

Roles in function

Full question: Included roles in your function. Please select all that apply.

Category	N	Percent of all	Percent of responders
Statisticians	29	93.5	100.0
Data Scientists	14	45.2	48.3
Quantitative Scientists	7	22.6	24.1
Pharmacometricians	4	12.9	13.8

Category	N	Percent of all	Percent of responders
Epidemiologists	4	12.9	13.8
Health Economists	3	9.7	10.3
Outcome Researchers	2	6.5	6.9
Programmers	20	64.5	69.0
Data Engineers	6	19.4	20.7
Data Managers	12	38.7	41.4
Other: Specify	5	16.1	17.2



Open answers for “Other: Specify”

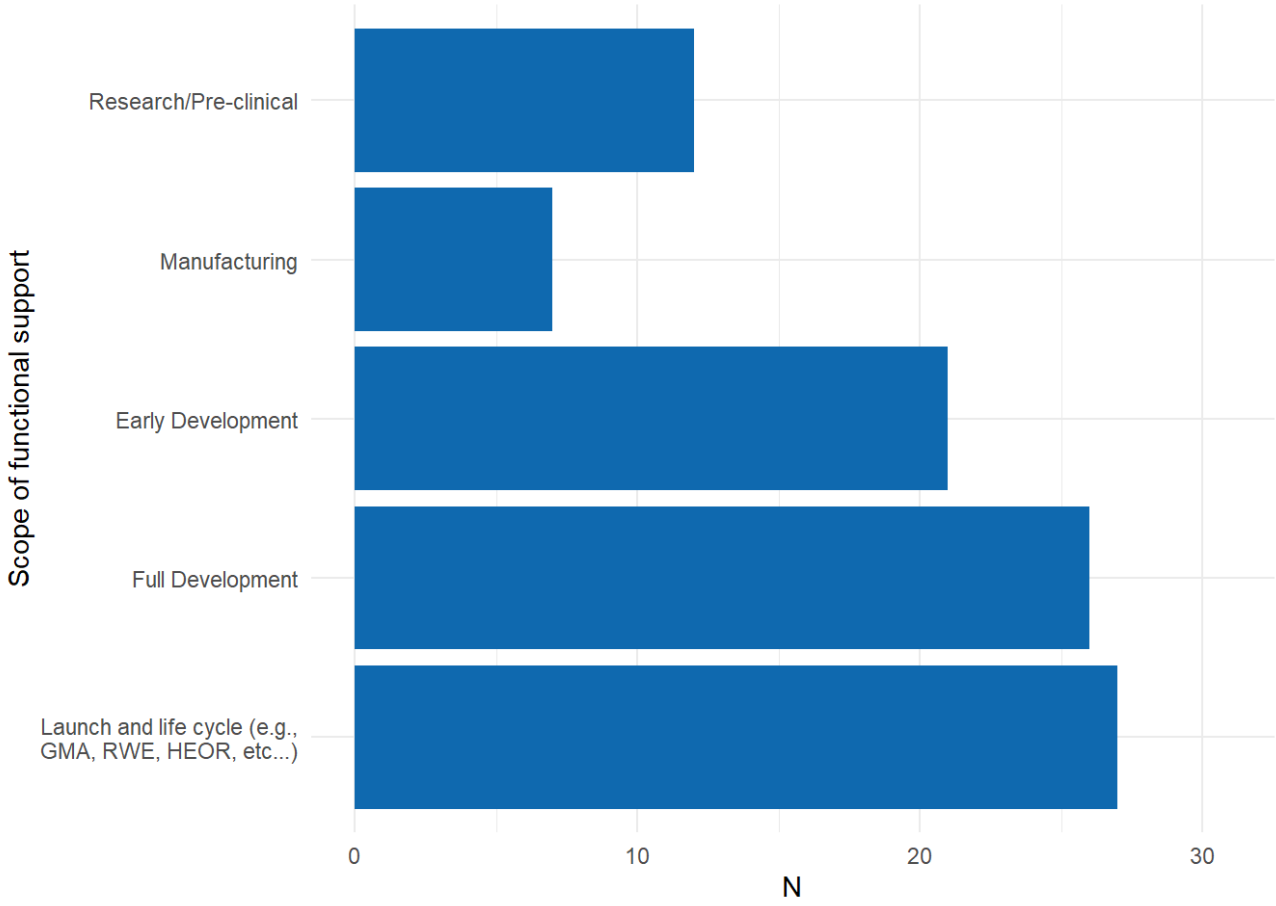
Answer	N
Agile Coaches	1
Clinical Trial Specialists	1
Data Platform technicians	1
Tool Developers	1

Answer	N
Tool developer	1

Scope of the functional support

Full question: Scope of the functional support. Please select all that apply.

Category	N	Percent of all	Percent of responders
Research/Pre-clinical	12	38.7	40.0
Manufacturing	7	22.6	23.3
Early Development	21	67.7	70.0
Full Development	26	83.9	86.7
Launch and life cycle (e.g., GMA, RWE, HEOR, etc...)	27	87.1	90.0



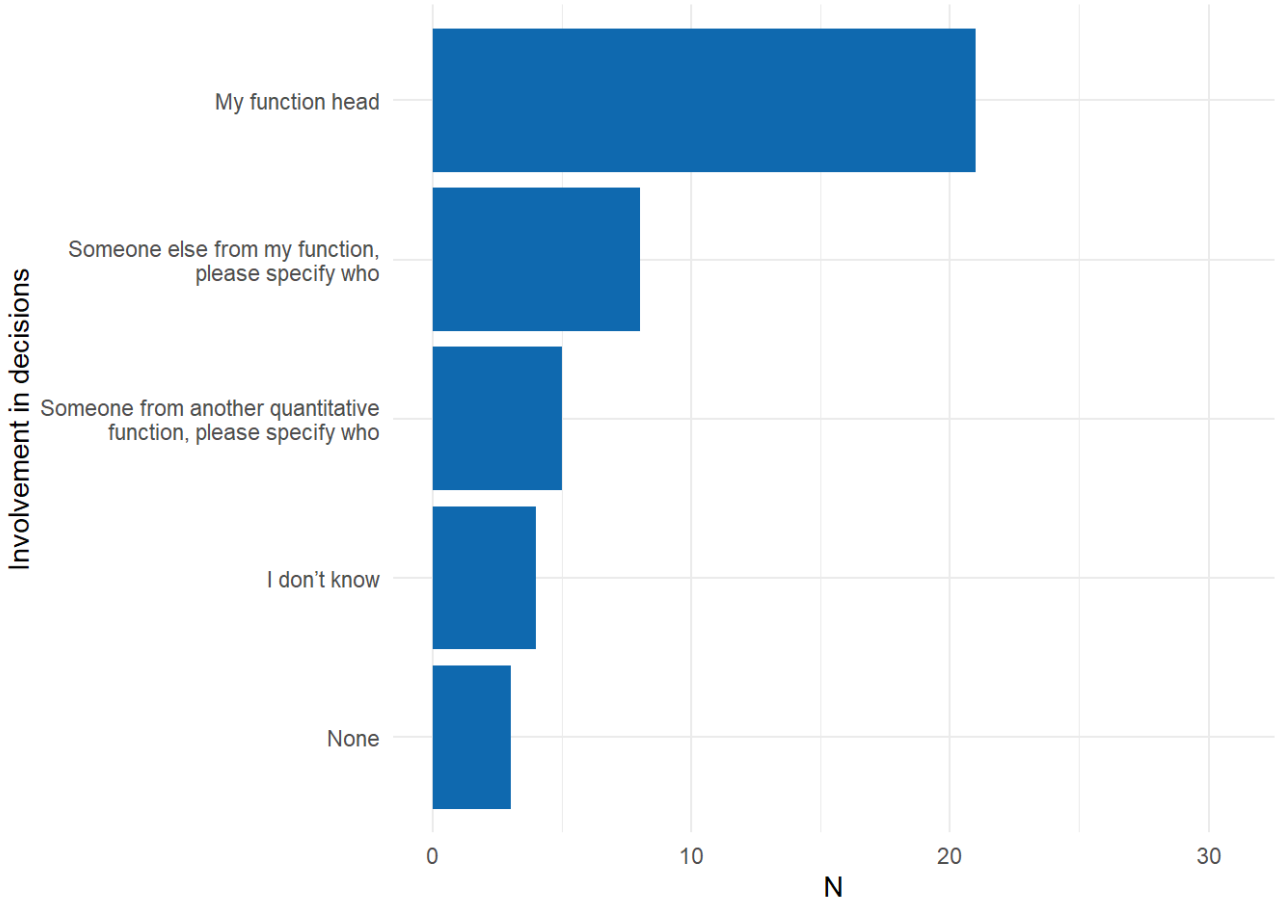
Status of strategic decision influence

Full session name: Current status of strategic decision influence

Involvement in decisions

Full question: In your organization, is someone with quantitative skills involved in strategic decision making at company / drug development organization level? Please select all that apply.

Category	N	Percent of all	Percent of responders
My function head	21	67.7	70.0
Someone else from my function, please specify who	8	25.8	26.7
Someone from another quantitative function, please specify who	5	16.1	16.7
I don’t know	4	12.9	13.3
None	3	9.7	10.0



Open answers

Open answers for “Someone else from my function, please specify who”

Answer	N
3 different levels of decision, head of stats sits at Governance (lowest of 3), Head of R&D sits at the highest level (CEO's staff)	1
Colleagues	1
Ex-FDA expert	1
Myself	1
Therapeutic Area/Development Unit Heads for their respective portfolios	1
VP Business Unit	1
myself and the methodology statistician	1

Open answers for “Someone from another quantitative function, please specify who”

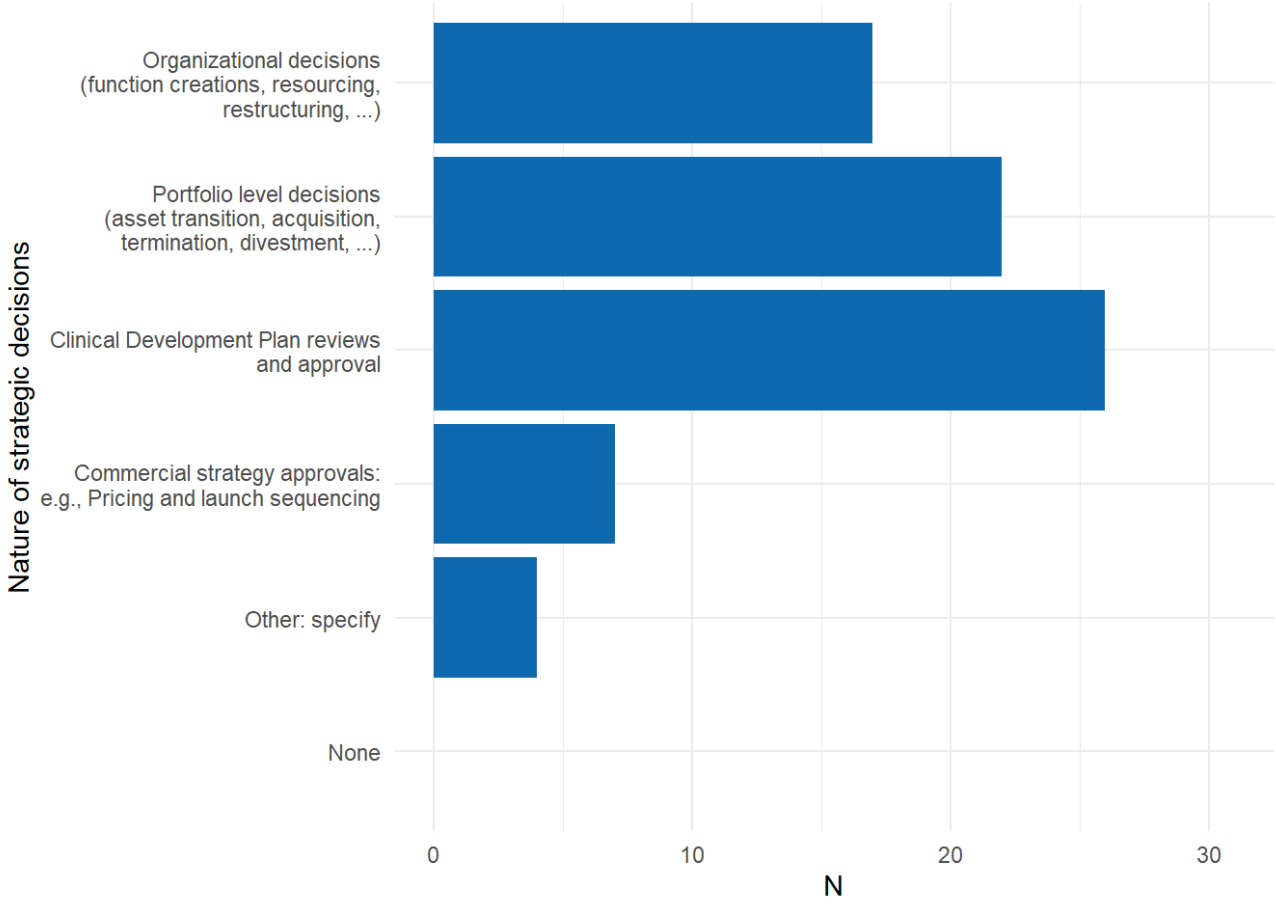
Answer	N
Clinical Pharmacology/Pharmacometrics	1
Head of Data Sciences	1
Head of Quantitative Pharmacology	1
Outcomes Research	1
Therapy area Biometrics heads	1

Nature of strategic decisions

Full question: Nature of Strategic Decisions supported by quantitative scientists/statisticians in your organization: Please select all that apply.

Category	N	Percent of all	Percent of responders
Organizational decisions (function creations, resourcing, restructuring, ...)	17	54.8	58.6
Portfolio level decisions (asset transition, acquisition, termination, divestment, ...)	22	71.0	75.9
Clinical Development Plan reviews and approval	26	83.9	89.7

Category	N	Percent of all	Percent of responders
Commercial strategy approvals: e.g., Pricing and launch sequencing	7	22.6	24.1
Other: specify	4	12.9	13.8
None	0	0.0	0.0



Answers to Other: specify

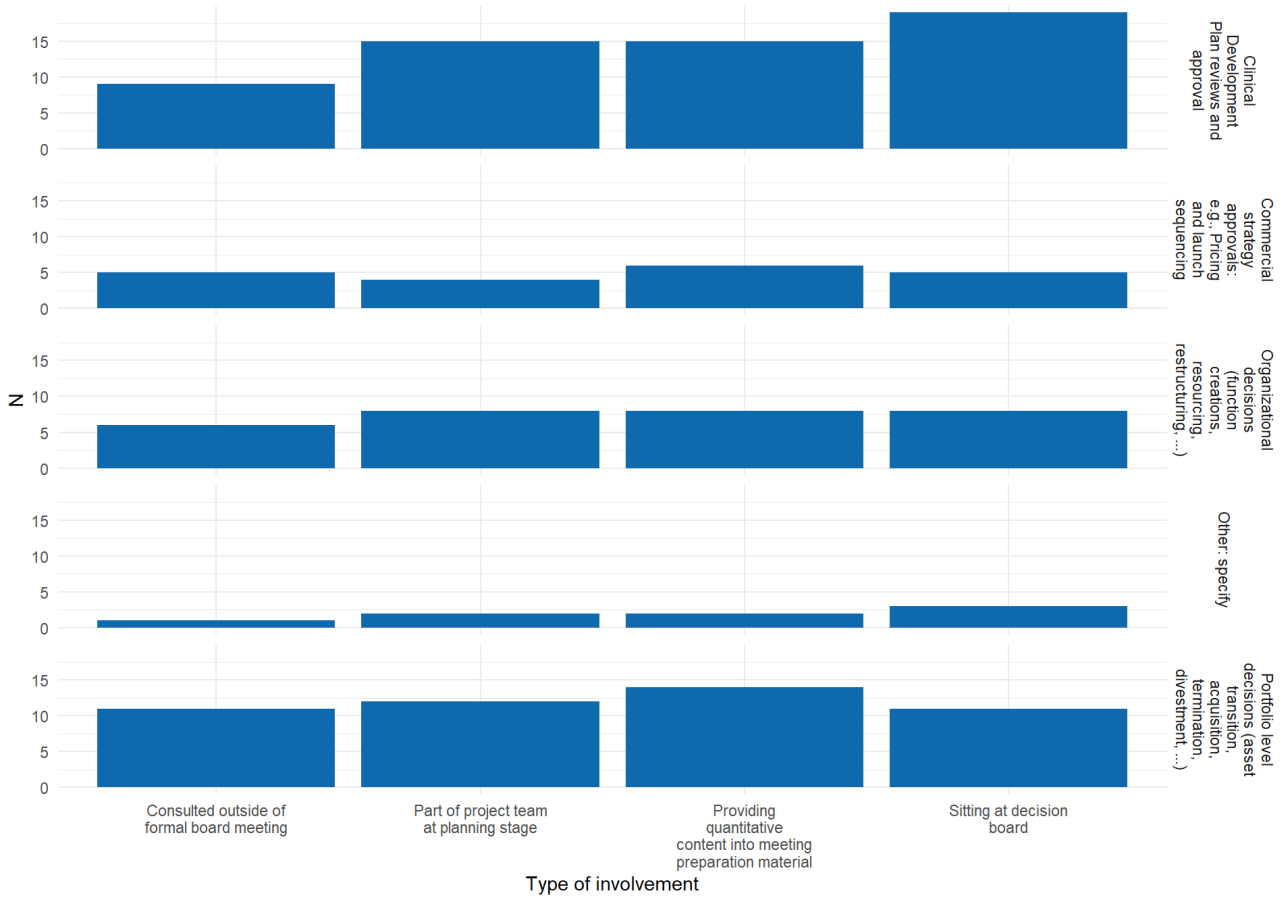
Answer	N
CMC strategy	1
HEOR, Observational Research	1
Research Review Board, Research Investment Board, Business Unit Strategy, Disease Area Strategy	1
Safety Signal Detection and Benefit/Risk decisions	1

Nature of involvement

Full question: Nature of quantitative scientist/statistician involvement: Please select all types of involvement that apply for each type of decision

In the table and figure, the number of participants is displayed that selected the respective option. Out of the 31 participants, 28 participants selected at least one option in at least one of the categories.

Type of decision	Consulted outside of formal board meeting	Part of project team at planning stage	Providing quantitative content into meeting preparation material	Sitting at decision board
Clinical Development Plan reviews and approval	9	15	15	19
Commercial strategy approvals: e.g., Pricing and launch sequencing	5	4	6	5
Organizational decisions (function creations, resourcing, restructuring, ...)	6	8	8	8
Other: specify	1	2	2	3
Portfolio level decisions (asset transition, acquisition, termination, divestment, ...)	11	12	14	11



Answers to Other: specify

Answer	N
CMC strategy	1
HEOR, Observational Research	1
Research reviews	1
SSD & /R	1

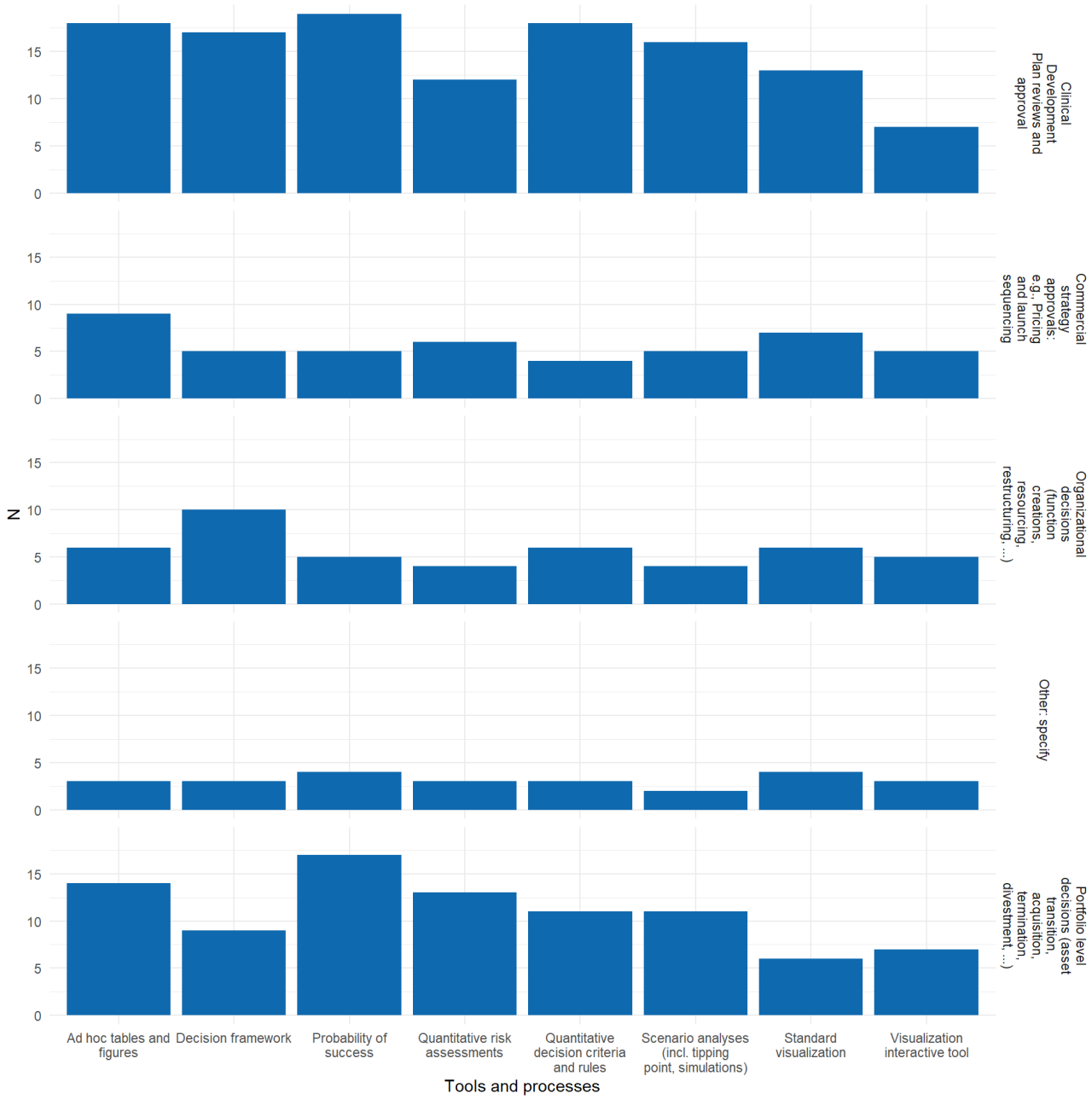
Tools and processes

Full question: In your organization, what are the main quantitative Tools & Processes used to support strategic decision making? Please select all tools and processes that apply for each type of decision

In the table and figure, the number of participants is displayed that selected the respective option. Out of the 31 participants, 28 participants selected at least one option in at least one of the categories.

Type of decision	Ad hoc tables and figures	Decision framework	Probability of success	Quantitative decision criteria and rules	Quantitative risk assessments	Scenario analyses (incl. tipping point, simulations)	vi
Clinical Development Plan reviews and approval	18	17	19	18	12	16	
Commercial strategy approvals: e.g., Pricing and launch sequencing	9	5	5	4	6	5	
Organizational decisions (function creations, resourcing, restructuring, ...)	6	10	5	6	4	4	
Other: specify	3	3	4	3	3	2	

Type of decision	Ad hoc tables and figures	Decision framework	Probability of success	Quantitative decision criteria and rules	Quantitative risk assessments	Scenario analyses (incl. tipping point, simulations)	vi
Portfolio level decisions (asset transition, acquisition, termination, divestment, ...)	14	9	17	11	13	11	



Answers to Other: specify

Answer	N
CMC strategy	1
HEOR, Observational Research	1
Research Review Board	1
SSD & B/R	1

Main enablers

Full question: Please provide the three main enablers for our influence and impact on strategic decision making

Raw key words per participant

Copy CSV Excel **Search:**

Key word 1	Key word 2	Key word 3
All	All	All
evidence-based culture	communication	competence
quantitative experience	tech saviness	openmindness
strong knowledge	leadership skills	company maturity
Communication	Business Acumen	
global vision	understanding	expertise
Understanding Big Picture	Communication skills	Upper Management Scientific and Quantitative mindset
Therapeutic Area Knowledge	Competitor Landscape Analysis	
internal network	understanding business context	reputation
Seat at table	Seat at next table (project team, governance team)	Communication to non-statisticians
objectivity in decision	methods that can easily be communicated and understood	

Showing 1 to 10 of 24 entries

Processed and consolidated key words

Copy CSV Excel **Search:**

Main enablers	n
All	All
Communication skills	5
Communication	4
Quantitative	4
Availability and visibility	3
Reputation	3
Trust	3
Evidence based culture	2
Logic	2
Science	2
Seat at table	2

Word cloud

Main hurdles

Full question: Please provide the three main hurdles for our influence and impact on strategic decision making

Raw key words per participant

Copy CSV Excel **Search:**

Key word 1	Key word 2	Key word 3
All	All	All
perfectionism	technical focus	obedient
risk aversion		
Statisticians!	Decision-maker Ego	Perceived unflexibility
resources	visibility	scope too small
Cryptic/complex language and deliverables	Narrow focus and lack of curiosity	Self perception and self censoring
ad-hoc (last minute)		

Key word 1	Key word 2	Key word 3
Seat at table!	Interpret as well as analyse	
statistics can be difficult to convey	resource constraints	
Numerical ignorance	Lacking statistical communication skills	Minority (few clinical contributors in a large decision board)
Resources	Risk	Budget

Showing 1 to 10 of 22 entries Previous 1 2 3 Next

Processed and consolidated key words

Copy CSV Excel **Search:**

Main hurdles	n
All	All
Resources	5
Budget	3
Ad hoc	2
Communication skills	2
Lack of stat courage	2
Nerdy communication	2
Risk	2
Too technical	2
Access to key stakeholders	1
Appearing as a doubter	1

Showing 1 to 10 of 46 entries Previous 1 2 3 4 5 Next

Word cloud

Academic partnerships

For all five questions in this session, participants were asked to both enter up to three key words each and optionally enter additional text in the free text field.

Pain points

Full question: From your perspective what are the pain points with data sharing?

Raw key words per participant

Copy CSV Excel **Search:**

Key word 1	Key word 2	Key word 3
All	All	All
contract setup	data privacy	resources
confidentiality	Microsoft	
Confidentiality	Data privacy	
contract	anonymization	

Key word 1	Key word 2	Key word 3
privacy / IP	clearance	quality
Managing patient consent	Anonymisation still allowing research	Transparency on derivation conventions
too complex		
lack on de-identication techniques secondary use	legal risk minimisation	
Anonymization	Resources (harder to prioritize)	Concerns about competitive advantage
understanding the designs of the trials	What did the patient consent for	

Showing 1 to 10 of 24 entries Previous 1 2 3 Next

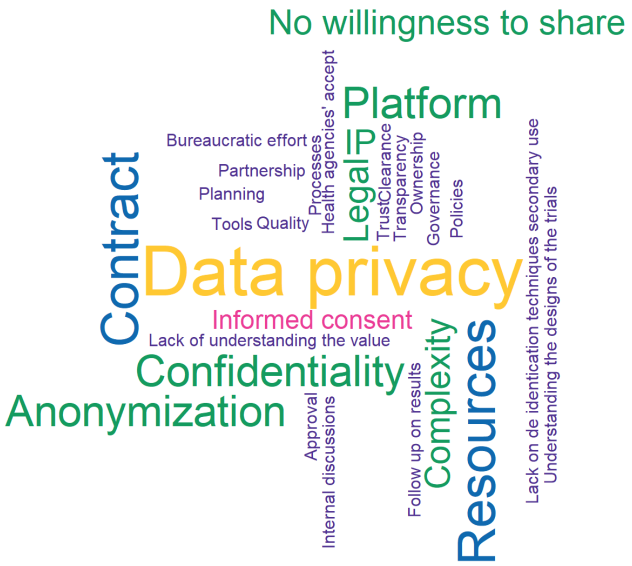
Processed and consolidated key words

Copy CSV Excel **Search:**

Pain points	n
All	All
Data privacy	7
Contract	5
Resources	5
Anonymization	4
Confidentiality	4
Platform	4
Complexity	3
IP	3
Legal	3
No willingness to share	3

Showing 1 to 10 of 30 entries Previous 1 2 3 Next

Word cloud



Responses in free text field

Copy | CSV | Excel

Search:

Answer
All
It's often not only the individual patient data, it's also the summary data. E.g. results based on data analyses are part of the Thesis which has to be public.
setting of data sharing agreement with academic institution required several cycle of review and intense interaction
N/A
GDPR is unclear what is acceptable to share patient data for secondary use as anonymised data seems not be that useful. What is acceptable and why is there no implementation guideline how to interpret GDPR text for concrete sharing of data
Complex process including GDPR requiremnents, statements in the IC, differention of the rules betweeen EU, USA, China,.. Lack of applicable platform for data sharing

Answer
Understanding whether anonymization process leds to a useful dataset that can help answer the research question. Process is very complicated and difficult to understand. Often takes a long time to get access.

Showing 1 to 6 of 6 entries

Previous 1 Next

Incentives

Full question: What incentives do you see for you to prioritize data sharing within your organization?

Raw key words per participant

Copy CSV Excel **Search:**

Key word 1	Key word 2	Key word 3
All	All	All
learning opportunity	better decisions	increase of PoS
informed decision making	informed value assessment	
Knowledge sharing	Efficencies	Consistencies
enhance knowledge on the disease of interest	better knowledge of use of drugs in real life	create synergies with academia/consortia
ICF language	Data Accesibility	
advertisement	(people)development	Science
maintaining strong academic network	increasing use of external data (ext controls, contextualization....)	Industry consortia (e.g., surrogate endpoint validation)
more comprehensive and consistent data source		
Transparency	Partnership/Collaboration	Research
awareness by sn management and legal	mandatory from outside	

Showing 1 to 10 of 26 entries

Previous 1 2 3 Next

Processed and consolidated key words

Copy CSV Excel **Search:**

Incentives	n
All	All
Reputation	7
Informed decision making	5
Increased knowledge	4
Collaboration	3
Resources	3
Increased collective knowledge	2
Innovation	2
Scientific insights	2
Accelerate	1
Benefits	1

Word cloud

Responses in free text field

Copy | CSV | Excel

Search:

Answer
All
Data is a treasure we should make use outside the key research question of a study (secondary use of data) within and across organisations. It anables us to learn about endpoints distribution/correlation; interpretation of safety signal, target population,Inclusion/exclusion criteria, etc.
build scientific knowledge
so far companies focus on the risks for their own company rather than the benefits for the overall industry. Incentives to shift this mindset will help
Data sharing rules should be harmonised and simplified. More resources and improved skills to handle data sharing
Having adequate resource (provided by other functions) to enable data sharing to be effective.
the biggest incentive is (a) everybody else is doing it and we willl be left behind; (b) either we are part of the solution or one will be imposed by EU

Showing 1 to 6 of 6 entries

Previous 1 Next

Value

Full question: What value has data sharing brought to your organization so far?

Raw key words per participant

Copy CSV Excel **Search:**

Key word 1	Key word 2	Key word 3
All	All	All
better decisions	increase of PoS	
informative business review meetings	opportunities for upselling	
better knowledge of epidemiology of specific disease	to enhance precision medecine	
business	visibility	expertise
Academic research collaboration (endpoints, methods, insights)	Regulatory agency research collaboration	Cross industry Consortia (results on endpoints), and platform trials
Partnership/Collaboration		
relationship KOL		
Miminal sadly		
Higher level of understanding clinical data		
None		

Showing 1 to 10 of 19 entries

Previous 1 2 Next

Processed and consolidated key words

Copy CSV Excel **Search:**

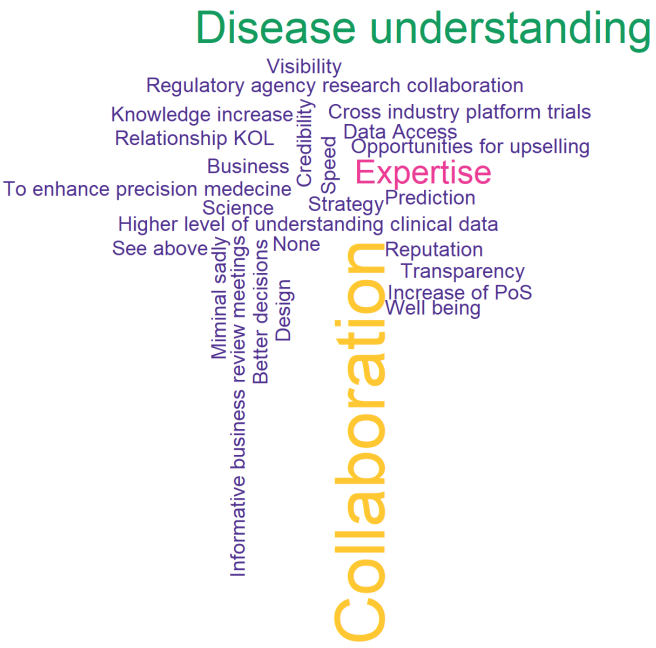
Value	n
All	All
Collaboration	5

Value	n
Expertise	2
Better decisions	1
Business	1
Credibility	1
Cross industry platform trials	1
Data Access	1
Design	1
Higher level of understanding clinical data	1

Showing 1 to 10 of 28 entries

Previous 1 2 3 Next

Word cloud



Responses in free text field

Copy CSV Excel

Search:

Answer
All
Better understanding on methodes applied and appropriness of methodology, e.g. SAVVY initiative
Developing the 3 points mentioned in Q 13.
N/A
Patients health and well being can be enhanced in collaboration with relevant stakeholders using scientific method
Better internal data sharing, helped with external collaborations and led to more informed changes in strategy.
It has not yet done so.

Showing 1 to 6 of 6 entries

Previous 1 Next

Platform trials

Full question: One complex area for data sharing is Platform trials which involve multiple sponsors. Such trials require sharing of control group data for the analysis of each arm. In addition, especially if non-concurrent controls are used, they may require also sharing of data from other experimental arms to be able to adjust for potential time trends. Do you have ideas how such data sharing can be implemented in a way that protects the sponsor’s interests and the integrity of the still ongoing platform trial?

Raw key words per participant

Copy CSV Excel **Search:**

Key word 1	Key word 2	Key word 3
All	All	All
independent data center	planning	publication plan
Use a third party (vendor - Berry's- or academic) to run the platform and deliver needed analyses	Prespecified and agreed analyses milestones, methods and data flow	extended IDMC mandate
concurrent		
?		
We haven't worked on these		
No		

Key word 1	Key word 2	Key word 3
Joint rules	Collaboration	Leading partner
Confidentiality Agreements	Charters	
imposed by law	ran by independant parties	
Use of third party vendors	Requirement to align on SAPs	Limit to pre-specified, jointly agreed analyses

Showing 1 to 10 of 12 entries Previous 1 2 Next

Processed and consolidated key words

Copy CSV Excel **Search:**

Platform trials	n
All	All
Independent data center	3
Collaboration	2
Limit to prespecified activites	2
Charters	1
Concurrent	1
Confidentiality agreements	1
Extended idmc mandate	1
Imposed by law	1
Incentives	1
Joint rules	1

Showing 1 to 10 of 19 entries Previous 1 2 Next

Word cloud

Responses in free text field

Copy CSV Excel **Search:**

Answer
All
To protect the sponsors interest a platform trial has to be set-up in a way that not only the winner get's it all if there is "sufficient" similarity between the treatments. At the end sponsors should accept a minimum transparency/sharing of data when joining such a trial. Thus, internal lobbying and accepting increased planning efforts [including the time associated to this] is an important element.
No but I am very interested in discussing
I have no specific experience so far
N/A
All participanting companies agree to share the same control group patients. Reporting of control group patients uses de-identified data to maintain study integrity.
Leading partner who lead/co-ordinates platform trials and confirm equally interests of all participating companies

Answer
I beleive that governments and health autorities should make platform trials mandatory.
EMA (and EU HTA) would like to see greater alignment across sponsors in their trial designs in general, in terms of data collected, frequence of data collection, instruments used, inclusion/exclusion criteria, etc, to enhance comparability across trials.

Showing 1 to 8 of 8 entries Previous 1 Next

Platform trials experimental arms

Full question: Usually, platform trials are set-up to enable comparisons of investigational treatments to a common control. How can data be shared for comparison between experimental arms in secondary research in a timely manner?

Raw key words per participant

Copy CSV Excel **Search:**

Key word 1	Key word 2	Key word 3
All	All	All
part of the contract	publication plan	
access control	integrity	
Upfront agreement between sponsors	Third party running the trial delivering systematic planned comparisons	
?		
Common CRO?		
Joint rules	Publicity	Time frame
performed by independant parties		
Alignment on trial design	publication of results by all subgroups	explore use of 3rd party vendors
Standards	Tools	Planning

Showing 1 to 9 of 9 entries Previous 1 Next

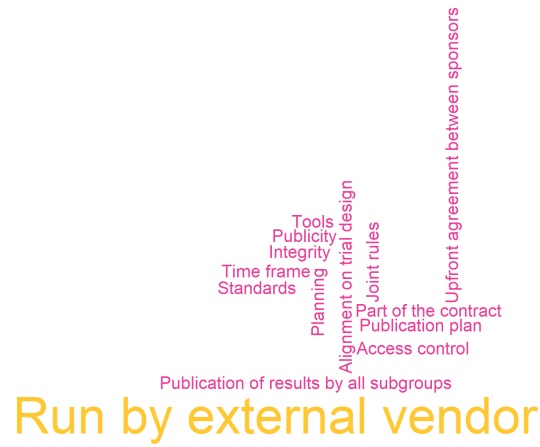
Processed and consolidated key words

Copy CSV Excel **Search:**

Platform trials experimental arms	n
All	All
Run by external vendor	4
Access control	1
Alignment on trial design	1
Integrity	1
Joint rules	1
Part of the contract	1
Planning	1
Publication of results by all subgroups	1
Publication plan	1
Publicity	1

Showing 1 to 10 of 14 entries

Word cloud



Responses in free text field

Copy CSV Excel **Search:**

Answer
All
In my view this is not in the first place a technical issue. It’s to reflect on this before the agreement of the contract is set-up. There is no free lunch and participation in a platform trial implies a comparison of the treatment arms. If not done professional within the trial, it will be done in the naïve way from the outside (e.g. by just comparing summary statistics provided in publications / clintrials.gov.
Have not worked on this application
N/A
Clear rules and transparency are required including time frame when secondary research is accepted
Biggest barrier is trust that such data is only used for the purpose it is intended and is not used to commercially disadvantage other companies' products.

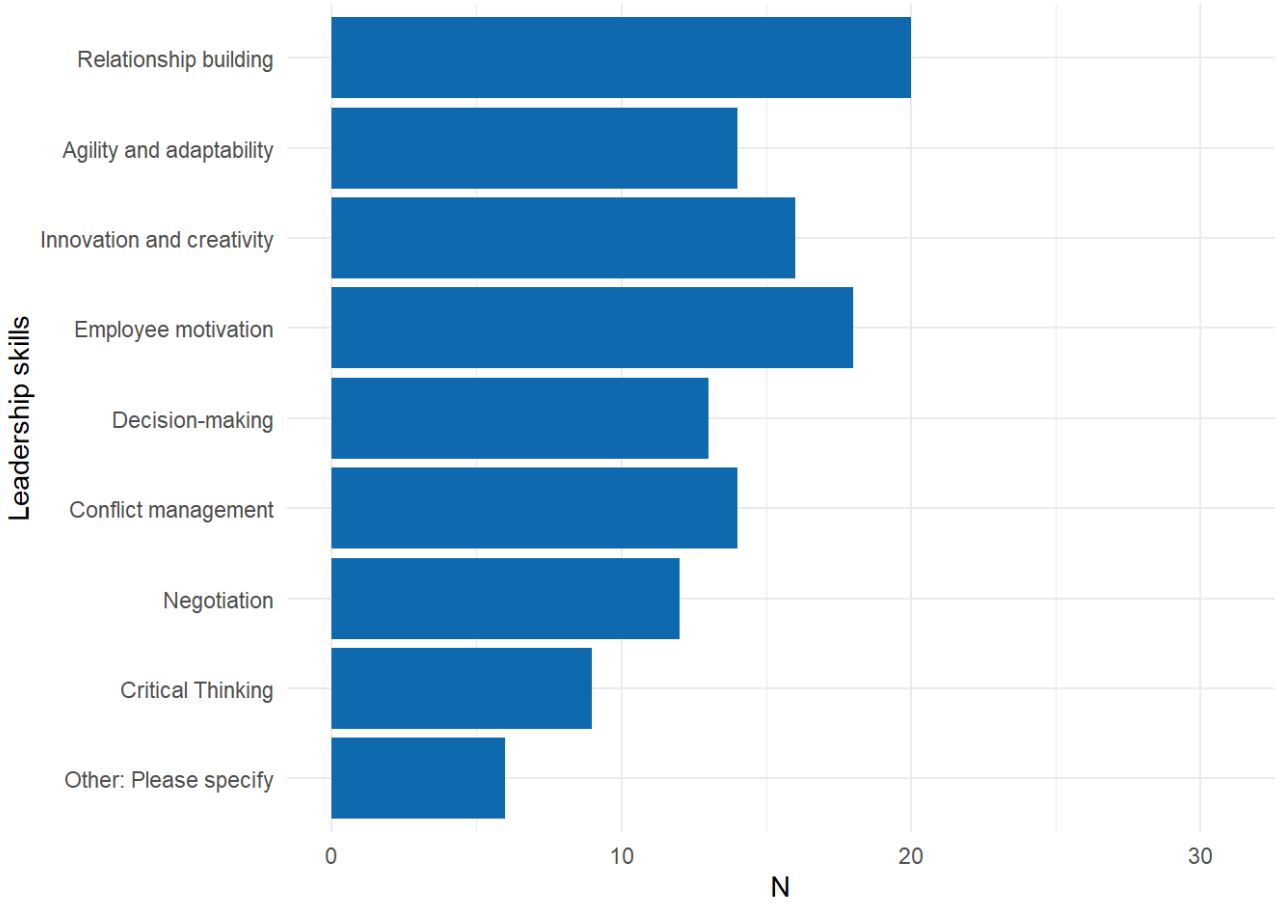
Leadership, management and future

Full session name: Leadership, management and future direction of Biostatistics

Leadership skills

Full question: Which of the following leadership skills are you developing as part of your career development? Please select all that apply.

Category	N	Percent of all	Percent of responders
Relationship building	20	64.5	71.4
Agility and adaptability	14	45.2	50.0
Innovation and creativity	16	51.6	57.1
Employee motivation	18	58.1	64.3
Decision-making	13	41.9	46.4
Conflict management	14	45.2	50.0
Negotiation	12	38.7	42.9
Critical Thinking	9	29.0	32.1
Other: Please specify	6	19.4	21.4



Open answers for “Other: Specify”

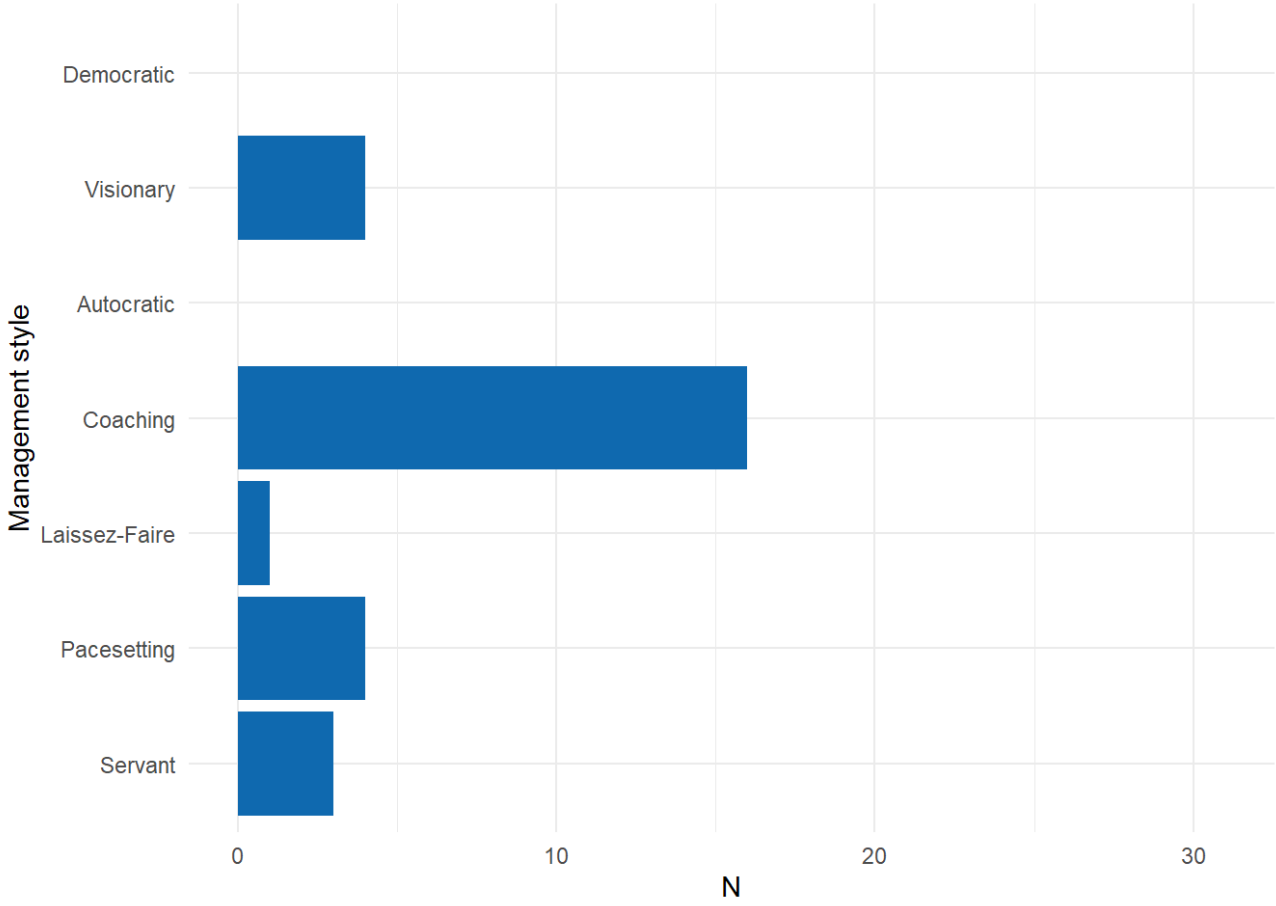
Answer	N
Authenticity	1
Business insights + stakeholder engagement	1
Listening, curiosity	1
coaching, mentoring, business acumen and political savvyness, transforming a vision	1
stakeholder management	1

Management style

Full question: Which of the following statements best reflects your management style?

Category	N	Percent of all	Percent of responders
Democratic	0	0.0	0.0
Visionary	4	12.9	14.3
Autocratic	0	0.0	0.0

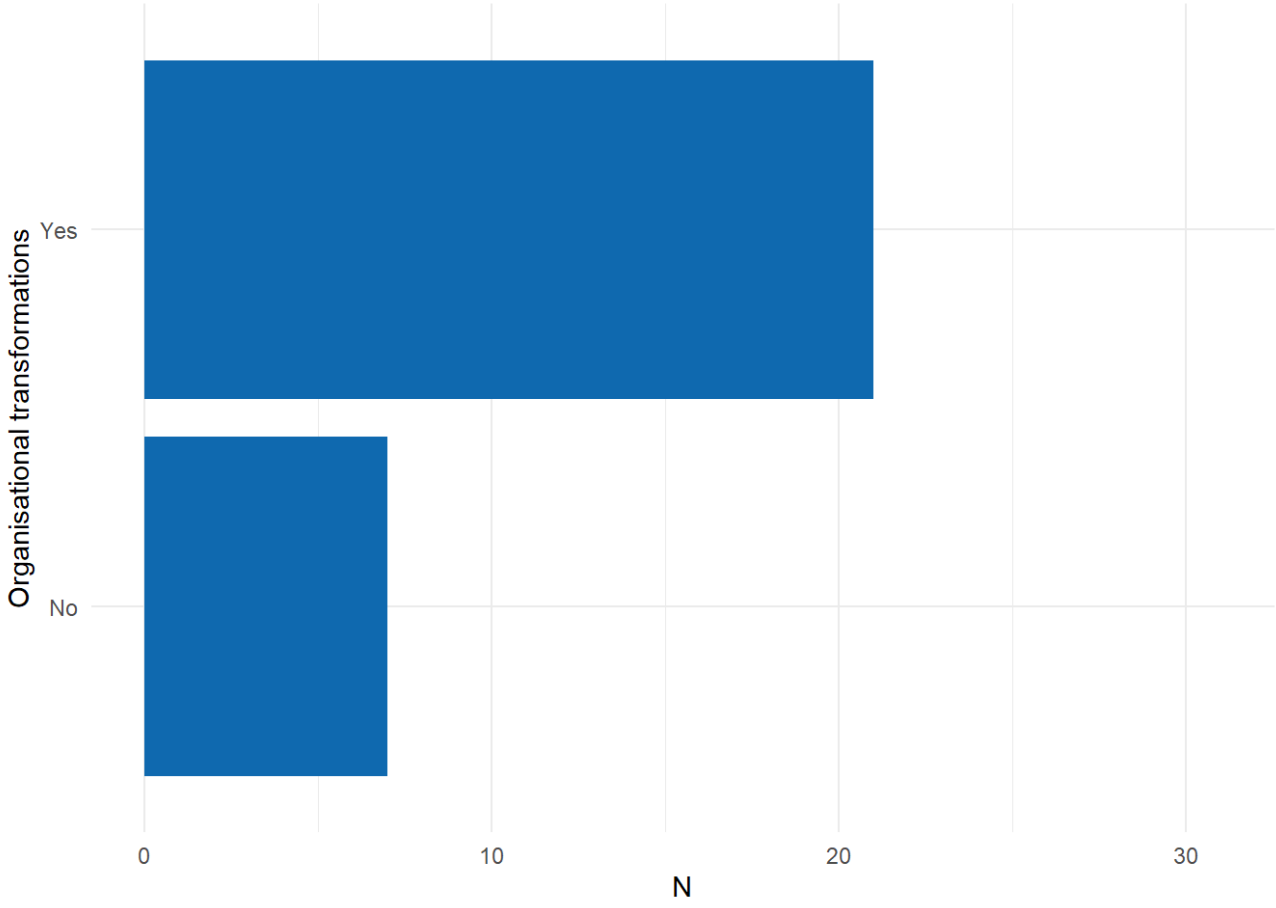
Category	N	Percent of all	Percent of responders
Coaching	16	51.6	57.1
Laissez-Faire	1	3.2	3.6
Pacesetting	4	12.9	14.3
Servant	3	9.7	10.7
NA	3	9.7	NA



Organisational transformations

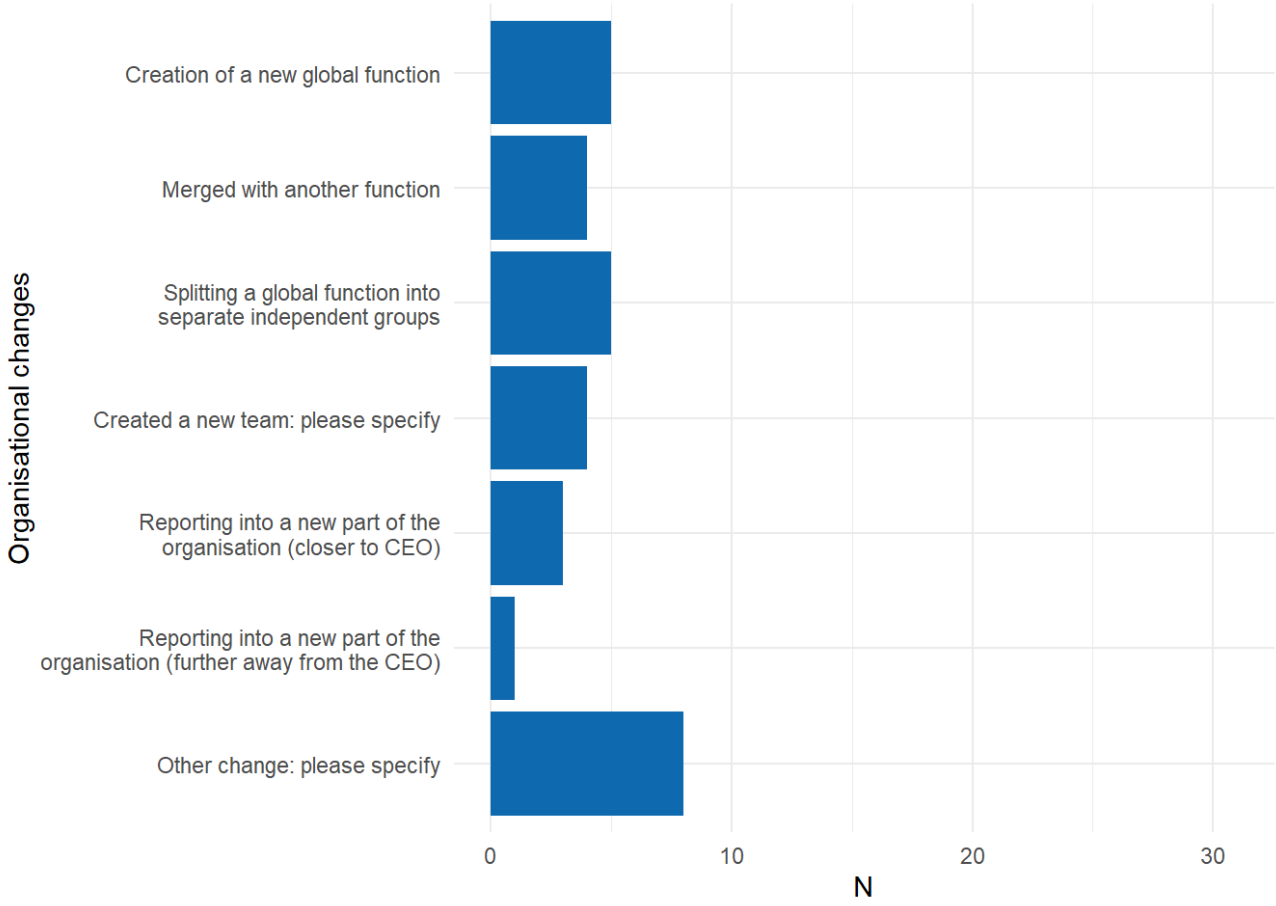
Full question: Has your Biostatistics function undergone, is going through or is planning to implement any major organisational transformations?

Category	N	Percent of all	Percent of responders
Yes	21	67.7	75.0
No	7	22.6	25.0
NA	3	9.7	NA



If yes, what type of changes have been / will be implemented?

Category	N	Percent of all	Percent of responders
Creation of a new global function	5	16.1	23.8
Merged with another function	4	12.9	19.0
Splitting a global function into separate independent groups	5	16.1	23.8
Created a new team: please specify	4	12.9	19.0
Reporting into a new part of the organisation (closer to CEO)	3	9.7	14.3
Reporting into a new part of the organisation (further away from the CEO)	1	3.2	4.8
Other change: please specify	8	25.8	38.1



Created a new team: please specify

Answer	N
Data Center team	1
Stat specialized for rare diseases and gene therapy	1
Statistics and Data Science Innovation Hub	1
structure the teams differently (smaller, more mixed)	1

Other change: please specify

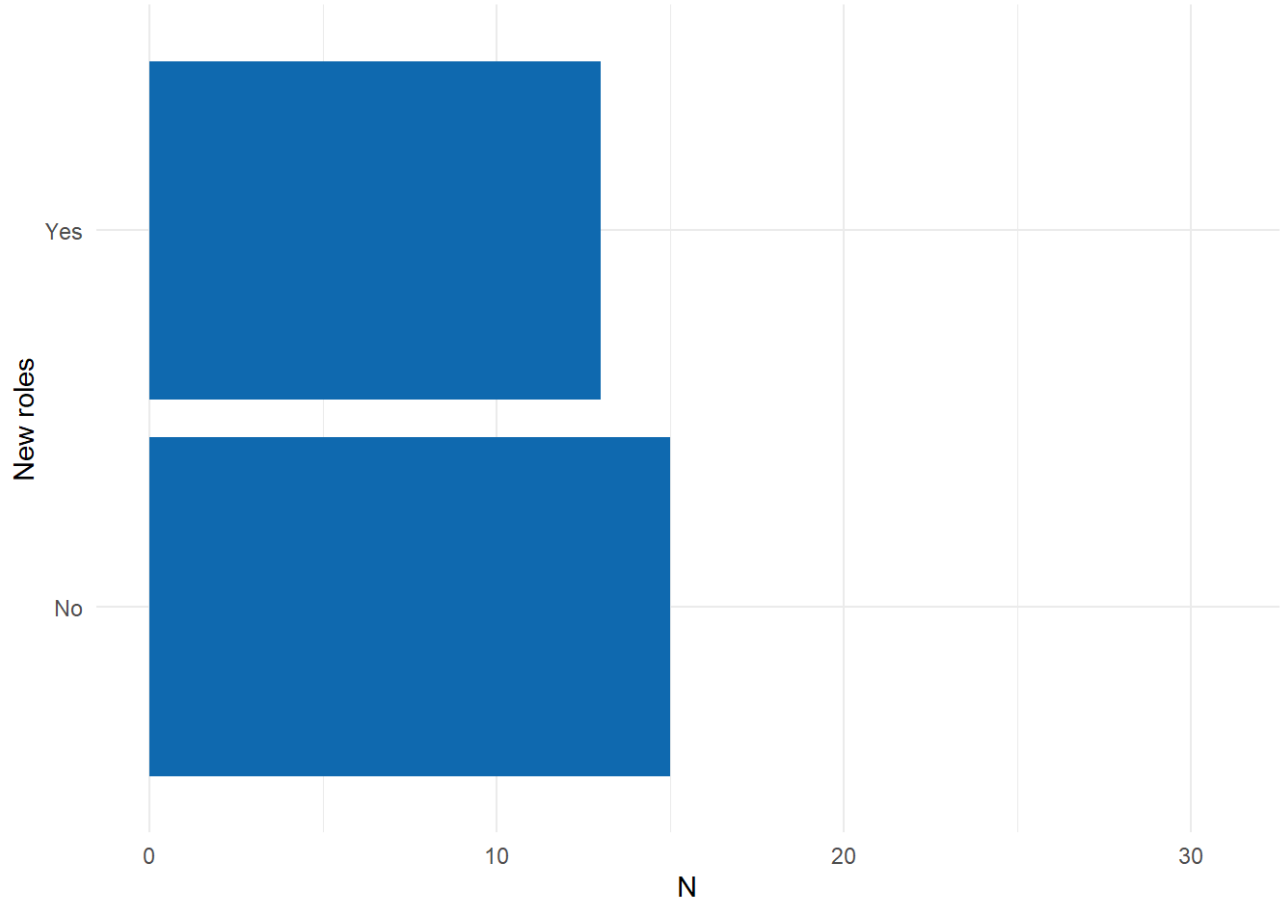
Answer	N
Adapting constantly to new requirements with merging or creating new teams and groups	1
Biostatistics is now part of a larger organisation which combines all major quantitative science departments within R&D.	1
Head of Stat is also Chief Data Officer (CDO) and hence closer to CEO	1
Part of a newly established SVP-area with DM, Pharmacometrix, Epidemiology, Advance Analytics and AI	1

Answer	N
Reduction of department	1
Various merges and splits within Biostatistics over time	1
moving up and down and between Clinical and Medical Affairs in a constantly changing environment	1

New roles

Full question: Have you created or are you planning to create new role(s) in your organisation?

Category	N	Percent of all	Percent of responders
Yes	13	41.9	46.4
No	15	48.4	53.6
NA	3	9.7	NA



If yes, please specify the new role(s) and grade

Full question: please specify the new role(s) and grade (e.g. below Director, Director, Senior Director, Executive Director, Vice President)

Answer	N
Evidence Leads, Product Owners, Advisors; these roles are independent of positions	1
Executive Director and Director roles.	1
Head Patient Data Center, below Director	1
Innovation Heads (Senior Director), Data Science Head (Senior Director), Data Scientists (Director and below)	1
Lead research Biostat (Director); Head of Stat & Progr Rare diseases (VP); Head of Data Office (SD)	1
PRO statistician, AMNOG statistician (below Director)	1
Senior Technical Biostatistics Roles	1
Statistical Innovation Hub, Visualization, R development, Safety, etc.	1
Submission expert (below Director)	1
Trial statistician (title tbd) due to moving to an in-house model. Building an expert team and inovation cluster	1
VP	1
now: below Director recent past: new Senior Director	1

Further evolvement

Full question: How do you think Biostatistics could further evolve in the future?

Free text answers

Copy CSV Excel **Search:**

Answer
All
Moving the mindset from Data Output to Data Insight
Assigned more prominent role in Global development/gatekeeper
How we utilise AI

Answer
Key driver of the clinical development plan, extended contribution during the development, with stronger focus on quantitative decision-making, strong collaboration with other departments (like translational and precision medecine or digital innovation), stronger network within and externally to the company, driver of innovative solutions to speed drug developement
Unfortunately I suspect there will be greater divergence between the views/skills and mindset of industry statisticians and those of statisticians within Regulatory agencies.
For now, Biostatistics are generally siloed to their topics (e.g. clinical, manufacturing, etc.). A biostatistics team should be transversal and and give insights on all strategic questions and possible topics in a digitally transformed world. High level functions should be able to support their team in this transversality.
Greater engagement to promote critical thinking and statistical judgement in partners and stakeholders (who have more and more direct access to statistical tools without the means to use them wisely) Greater flexibility and openness to support real time data analysis, discusions and decision processes More use of graphical and interactive tools Greater influence in structuring key drug development processes, issues and decision making (dose optimization, portfolio prioritization, asset valuation, integrated evidence generation, result contextualization, ...) More and more involved in generalized risk identification, communication, quatification and mitigation strategies
broadening the scope beyond clinical is vital to survive other than a niche profession
Expand from core responsibilities (design and reporting) to embrace additional areas, eg centralised statistical monitoring
Strategising drug development programs to address healthcare policy issues at national, regional and global levels

Showing 1 to 10 of 22 entries Previous 1 2 3 Next

Top 20 key words according to ChatGPT

Copy CSV Excel Search:

Further evolvement	n
All	All
Data insight	2
AI	2
Clinical development	2
Quantitative decision-making	1

Further evolvement	n
Collaboration	1
Translational medicine	1
Precision medicine	1
Digital innovation	1
Network	1
Innovative solutions	1

Showing 1 to 10 of 20 entries Previous 1 2 Next

Word cloud based on ChatGPT key words

Additional analyses

Number of words per key word