

Anonymisation Strategies for Policy 0070 and PRCI Submissions

Stuart Donald, Co-CEO



Quantitative/Risk Based
Transformation



Qualitative/Rules Based
Redaction-only

Regulatory compliance?



Data privacy?

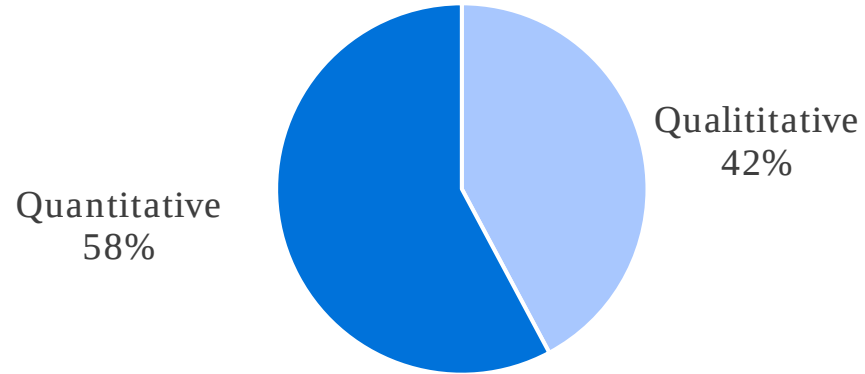
Data utility?

Time and cost?

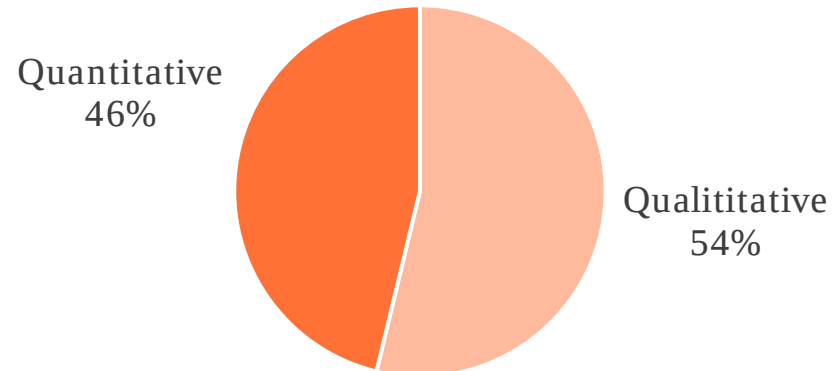
50:50 split in quantitative/qualitative methodologies seen in recent submissions



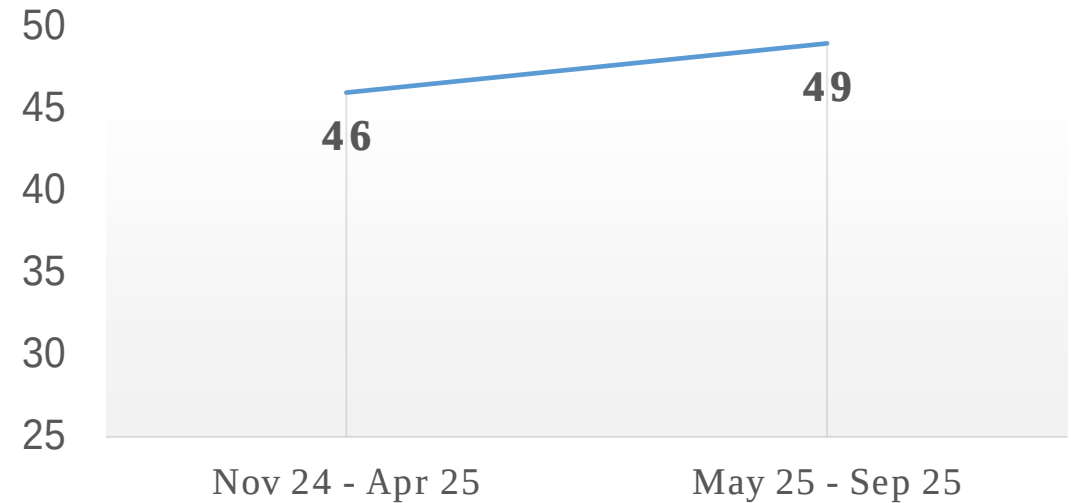
Policy 0070 (n=67)



PRCI (n=188)



% of packages using quantitative/risk based methodology



Analysis from 255 Policy 0070 /PRCI submissions from 88 companies
Nov 2024 to Sep 2025

Common justifications for taking a qualitative approach*



- **Resource constraints**
- **Time/efficiency**
- **Approach had been previously accepted by regulators**

We wanted to understand better why companies choose a particular anonymisation strategy for their Policy 0070 and PRCI submissions

**from published anonymisation reports*

Survey Design



- **38 companies** with recent Policy 0070 or PRCI submissions were invited in February 2026 to participate in an on-line survey comprising 20 questions
- **22 companies** provided responses (58% response rate)
 - Large (Top 10 by 2025 R&D spend) 6
 - Medium (2025 R&D spend >\$1Bn to <\$3Bn) 7
 - Small (2025 R&D spend <\$1Bn) 9

Respondents were very experienced in Policy 0070 and PRCI submissions



Policies respondents have supported

Both	17
PRCI only	3
Policy 0070 only	2

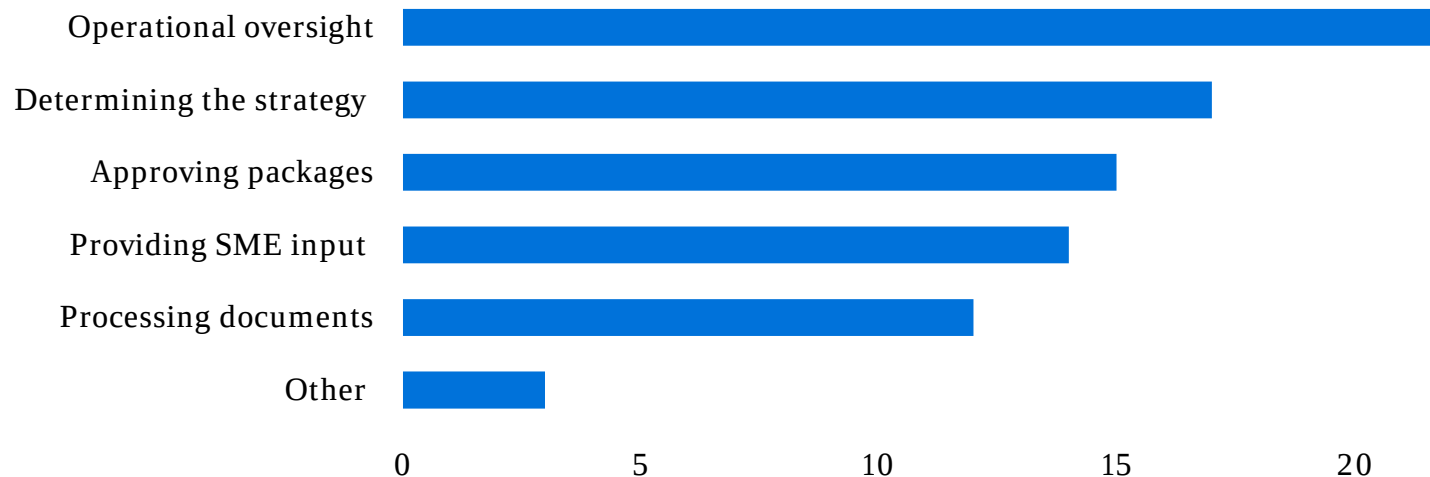
Familiarity with Policy 0070 and PRCI

Very familiar	15
Somewhat	7
Not familiar	0

Number of packages supported

1-10	12
Over 10	10

Activities respondents support in package preparation

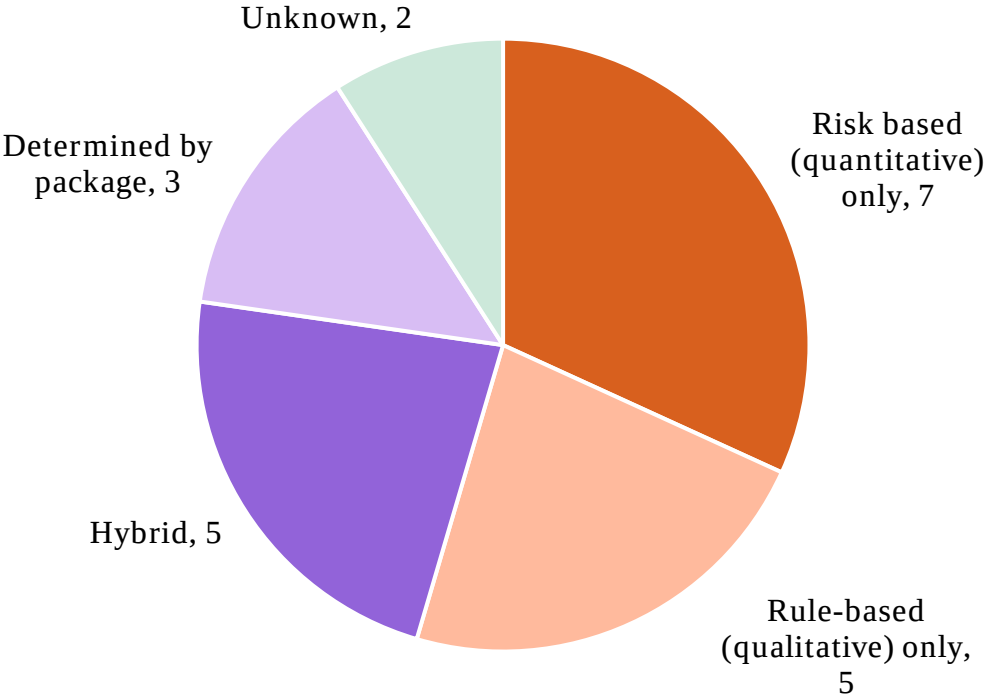


Department respondents are part of*

Clinical Trial Transparency	13
Regulatory	8
Medical Writing	7

**multiple responses could be selected*

Company's preferred anonymisation approach



Company Size	Risk-based only	Rule-based only	Hybrid/by package
Large	4	0	2
Medium	1	2	4
Small*	2	3	2

*2 respondents from small companies answered “unknown”

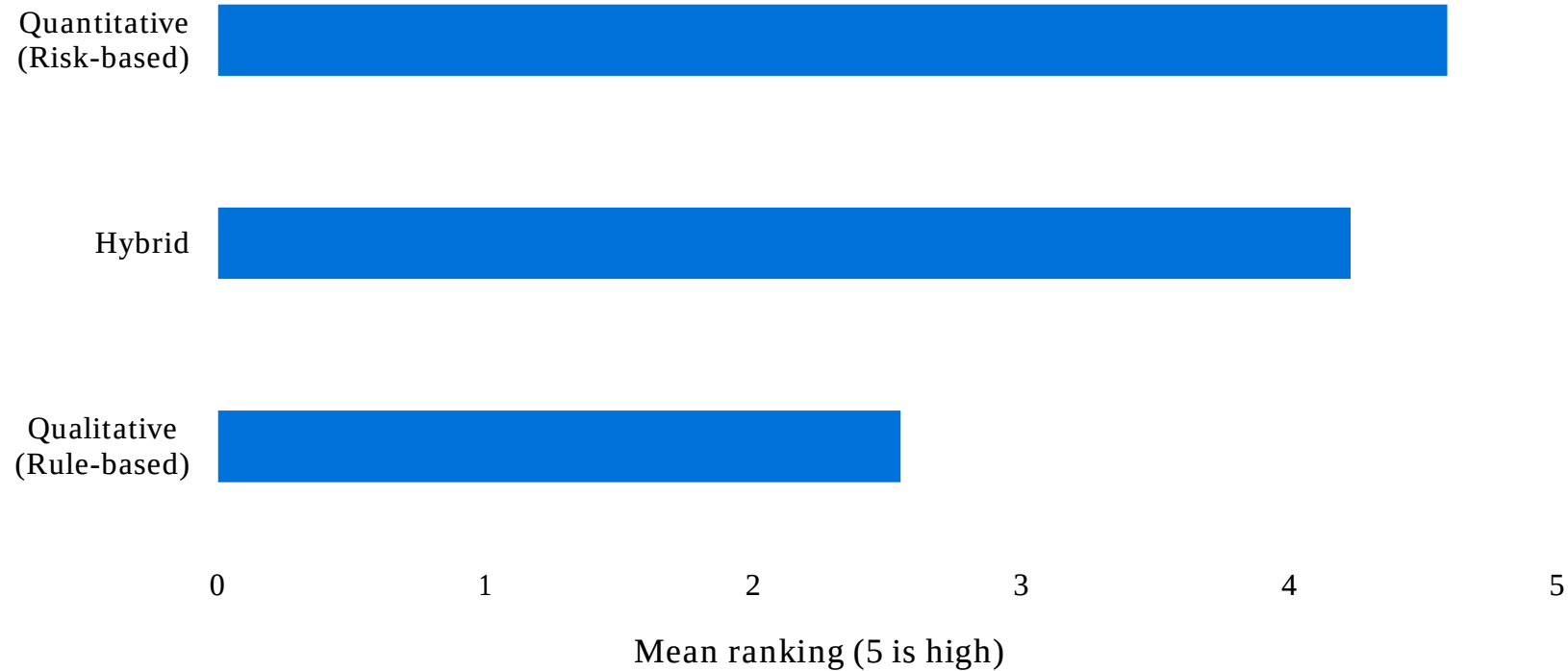
6/7 of the companies using a quantitative-only approach have always used this as their preferred strategy

- Is the same approach used for all studies in a package?
- Yes 59%
 - No (population based) 36%

Quantitative strategies score highest for regulatory acceptability



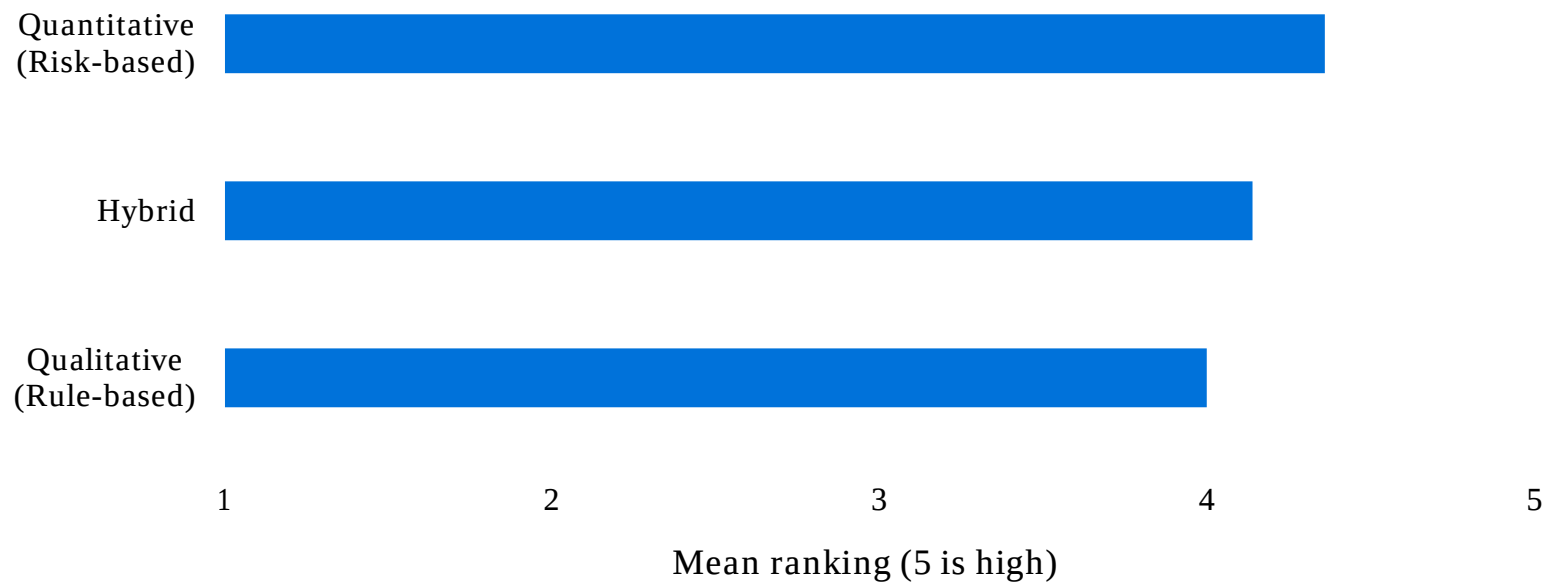
How compliant with regulations and health authority expectations are types of anonymisation strategy?



Quantitative methods are also perceived as providing the strongest privacy protection



Which anonymisation approach best protects personal data?



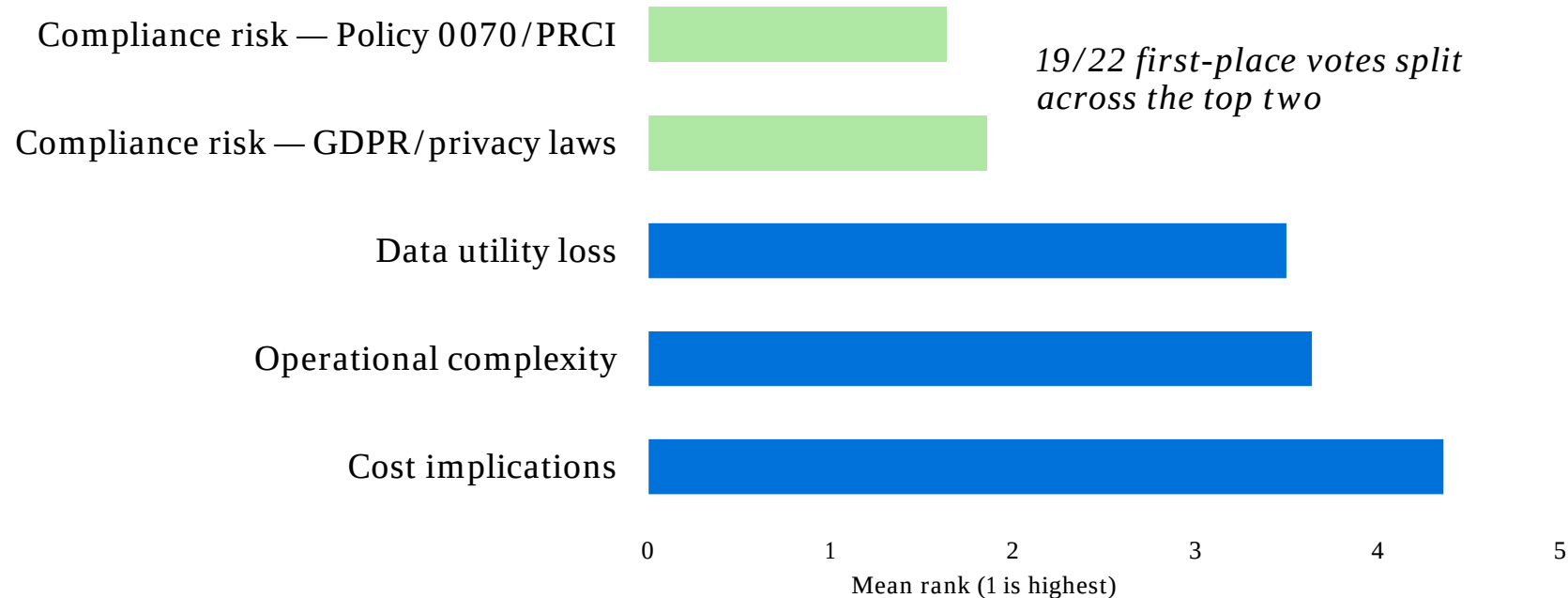
Risk thresholds applied

- High protection (<0.09) n=17
- Flexible (based on package type) n=2
- Don't know/na n=3

Compliance with regulations and protecting privacy are the most important factors in strategy selection



Relative importance when selecting an anonymisation strategy

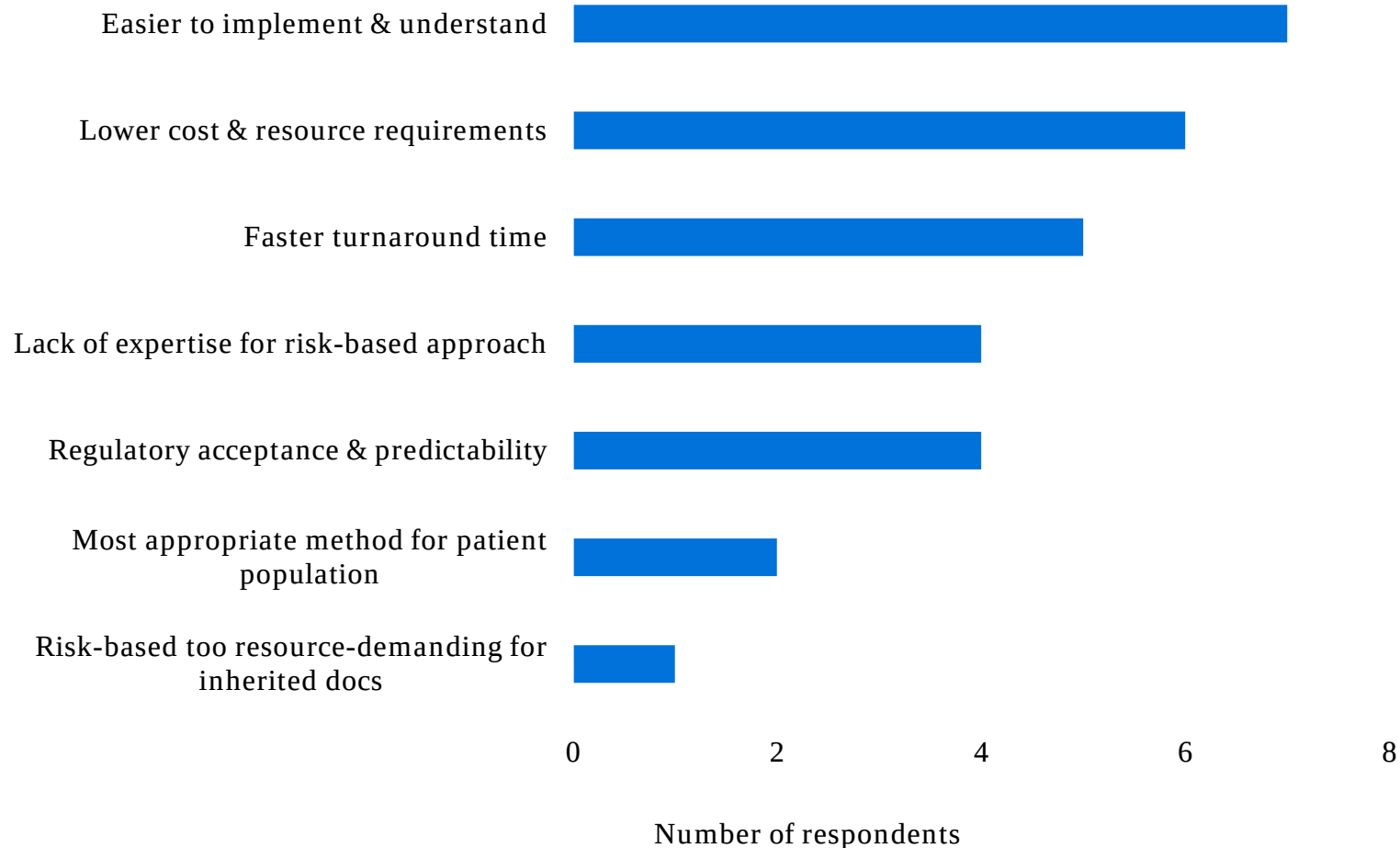


**Respondents were asked to rank reasons from 1 to 5, with 5 being the most important*

Ease of implementation, cost and speed are factors driving qualitative approaches

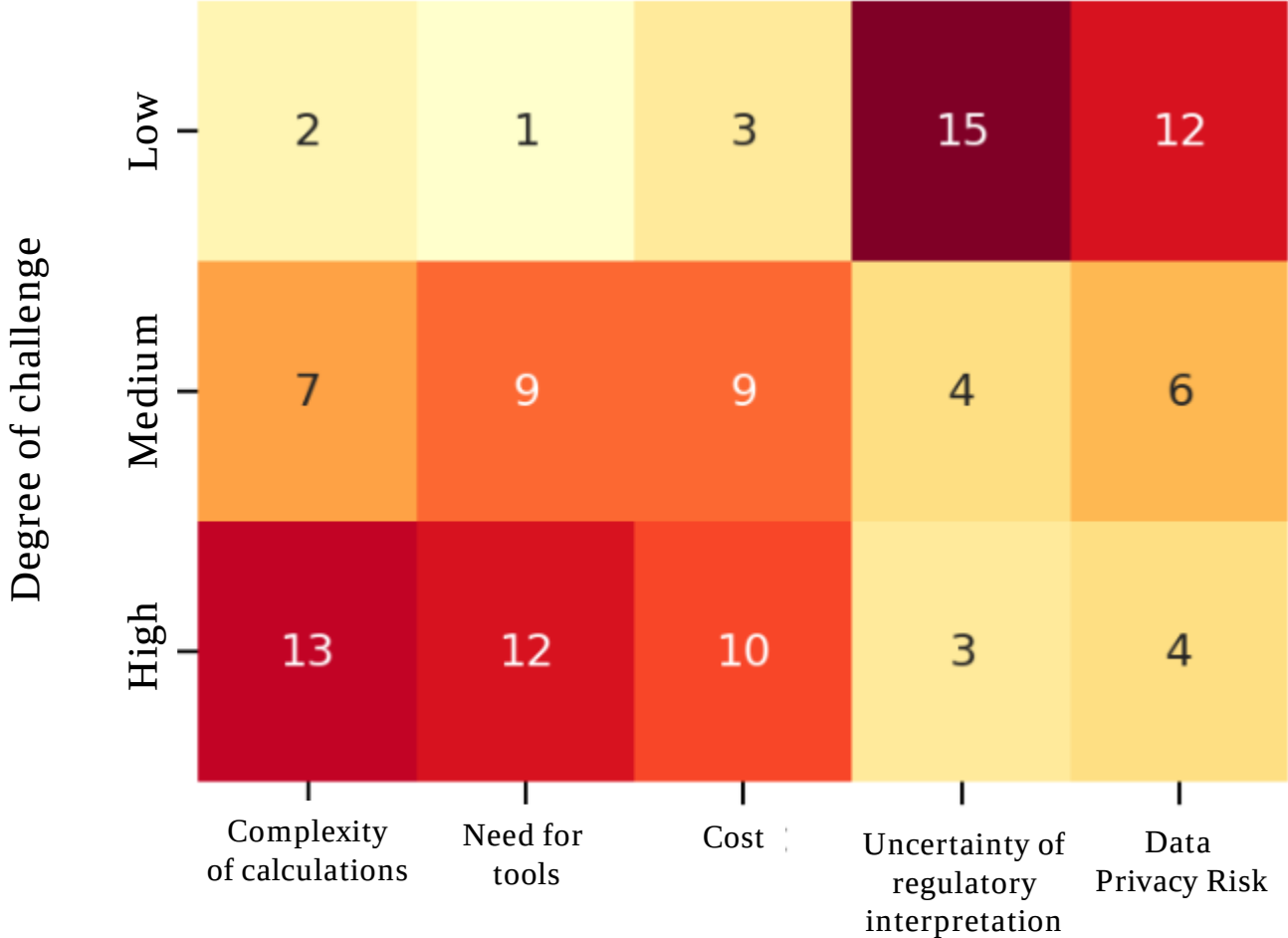


Main reasons for selecting a rule-based (qualitative) approach



**Respondents could select multiple answers. 14 respondents provided answers*

Complexity and need for specialised tools are seen as the main challenges with risk-based approaches



N=number of respondents

Operational and resource considerations



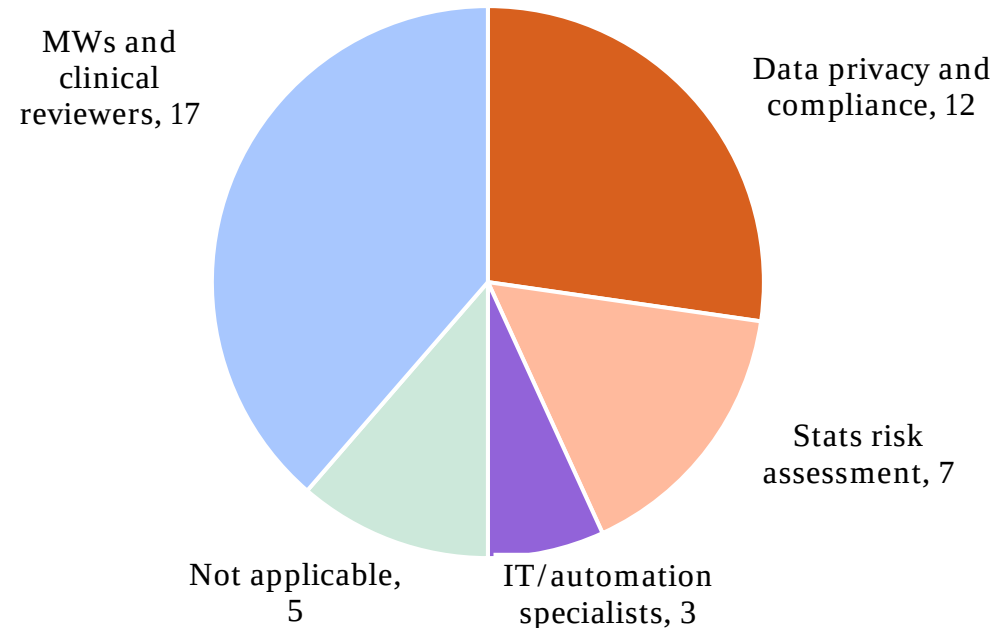
Use of technology

- Fully automated 3
- Fully manual 4
- Hybrid (automated tool/manual review) 15

Sourcing

- In-house, dedicated team 4
- In-house without dedicated team 1
- Partially outsourced 17

Roles kept in house (if outsourcing used)



Other considerations noted by respondents when selecting a strategy*



- Submission timelines
- Internal capabilities
- Types CSR (final vs interim, blinded etc)
- How to align across all documents and submissions for an asset
- Availability/format of datasets
- Complexity of descriptive statistics means risk-based is unfeasible
- Inability to consistently estimate data utility drives a more conservative approach

**summary of free text comments*

Conclusions

1. Industry is moving toward quantitative and hybrid strategies.
 - Adoption depends on data availability, study population sensitivities, and organisational capability.
2. Quantitative methods are perceived to be the most compliant and the most protective.
 - However, they remain resource-intensive and technically demanding.
3. Operational barriers, not regulation, are the primary constraints.
 - Complexity, tooling, and expertise drive the choice toward rule-based or hybrid approaches.
4. Hybrid strategies are being considered
 - These provide flexibility, reduce risk, and balance transparency with privacy.

Krystelis

Making clinical research crystal clear

Let's collaborate!

Dr Pooja Phogat
e: pooja.phogat@krystelis.com
m: +91 9810 889208

Dr Stuart Donald
e: stuart.donald@krystelis.com
m: +44 7806 565974