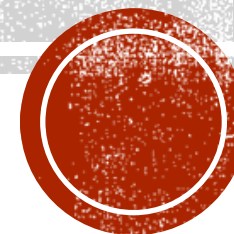


2025 PPAR PAT BENCHMARKING SURVEY*



Assembled by:

Elyse DiMaso – Bristol Myers Squibb

**Content is generated and for the use by members of the PPAR Community during the Annual Meeting 13-14 NOV 2025.*

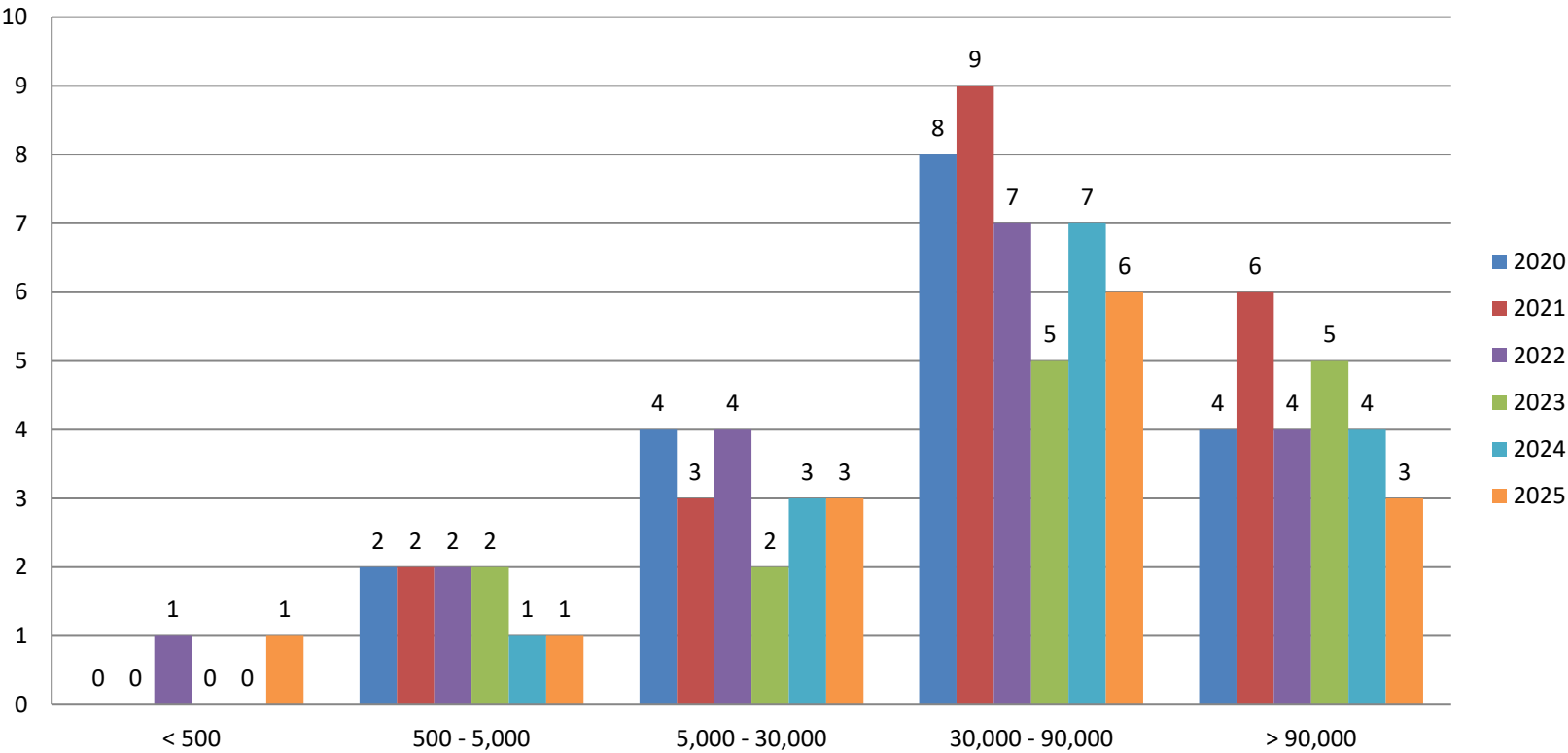
SURVEY DEMOGRAPHICS

Survey Respondents 2025 (14)

Abbvie
AstraZeneca
Amgen
Bristol Myers Squibb
Glaxosmithkline
Eli Lilly
Hovione
Moderna
Recipharm Advanced Bio
Roche-Genentech
Sanofi
Takeda Pharmaceuticals
Vertex Pharmaceuticals
Merck

Maintaining lower level of responses
2025: 14
2024: 15
2023: 14
2022: 18
2021: 22
2020: 18

Approximately how many employees at your company?



SURVEY DEMOGRAPHICS

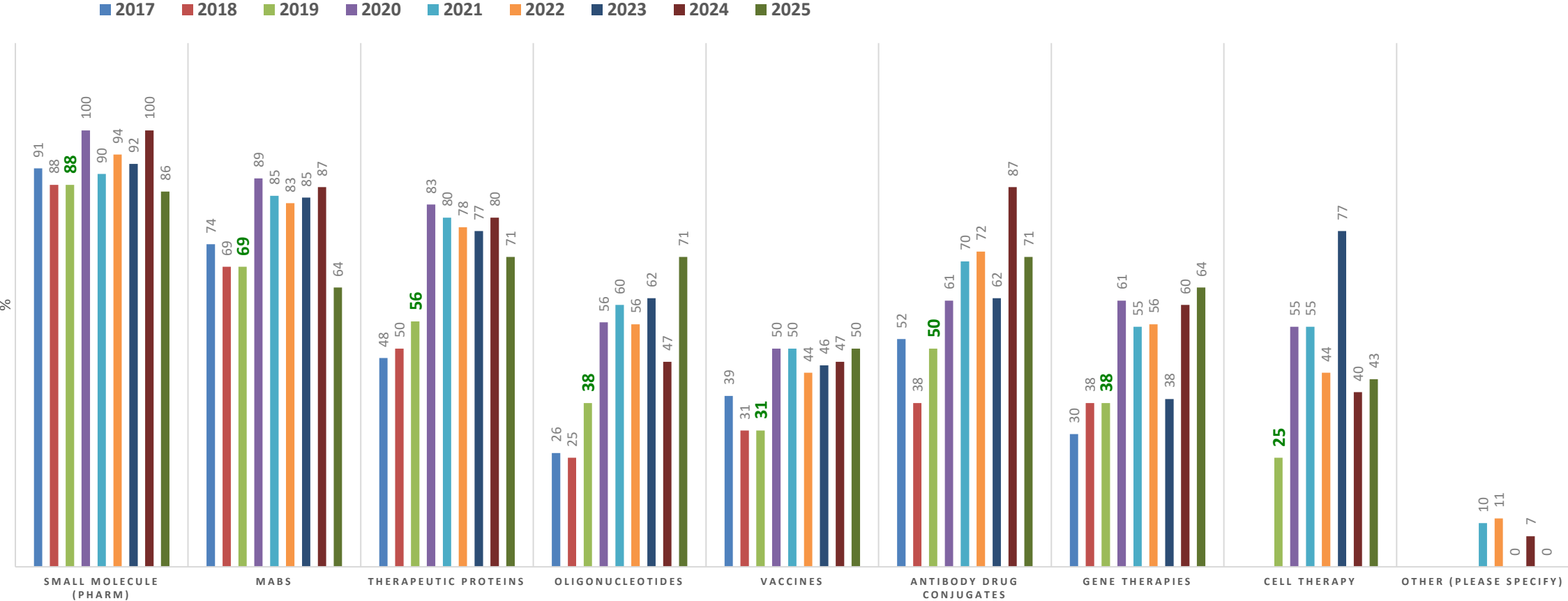
Survey Respondents 2020 (18)	Survey Respondents 2021 (22)	Survey Respondents 2022 (18)	Survey Respondents 2023 (13)	Survey Respondents 2024 (14)	Survey Repondents 2025 (13)
AbbVie	AbbVie	AbbVie	AbbVie	AbbVie	AbbVie
Amgen	Amgen	Amgen		Amgen	Amgen
AstraZeneca	AstraZeneca	AstraZeneca	AstraZeneca	AstraZeneca	AstraZeneca
Biogen	Biogen	Biogen	Biogen	Biogen	
Bristol Myers Squibb	Bristol Myers Squibb	Bristol Myers Squibb	Bristol Myers Squibb	Bristol Myers Squibb	Bristol Myers Squibb
Eli Lilly and Company	Eli Lilly and Company	Eli Lilly and Company		Eli Lilly	Eli Lilly
GlaxoSmithKline	GlaxoSmithKline	GlaxoSmithKline	GlaxoSmithKline	GlaxoSmithKline	GlaxoSmithKline
Hovione FarmaCiência S.A.	Hovione farmaciência s.a	Hovione farmaciência s.a	Hovione farmaciência s.a		Hovione
JnJ/Janssen Pharmaceuticals	JnJ/Janssen Pharmaceuticals	JnJ/Janssen Pharmaceuticals	JnJ/Janssen Pharmaceuticals	JnJ/Janssen Pharmaceuticals	
		Lyndra Therapeutics			
Merck	Merck	Merck		Merck	Merck
	Novo Nordisk	Novo Nordisk	Novo Nordisk		
Pfizer Inc	Pfizer Inc	Pfizer Inc		Pfizer	
Roche/Genentech	Roche/Genentech	Roche/Genentech	Roche/Genentech	Roche/Genentech	Roche
Sanofi S.A.	Sanofi S.A.	Sanofi S.A.	Sanofi S.A.	Sanofi S.A.	Sanofi
Takeda Pharmaceuticals	Takeda Pharmaceuticals	Takeda Pharmaceuticals	Takeda Pharmaceuticals	Takeda Pharmaceuticals	Takeda
Thermofisher Scientific Inc	ThermoFisher Scientific	Thermofisher Scientific Inc			
Vertex Pharmaceuticals Inc	Vertex Pharmaceuticals Inc	Vertex Pharmaceuticals Inc	Vertex Pharmaceuticals Inc	Vertex Pharmaceuticals Inc	Vertex Pharmaceuticals Inc
	CPAC - University of Washington				
	The Procter & Gamble Company				
	University of Massachusetts Lowell				
Zoetis	Zoetis				
			Regeneron		
					Moderna
					Recipharm Advanced Bio



PRODUCT TYPES

- Overall: good consistency
- This year, increase in Oligonucleotides and decrease in mABs

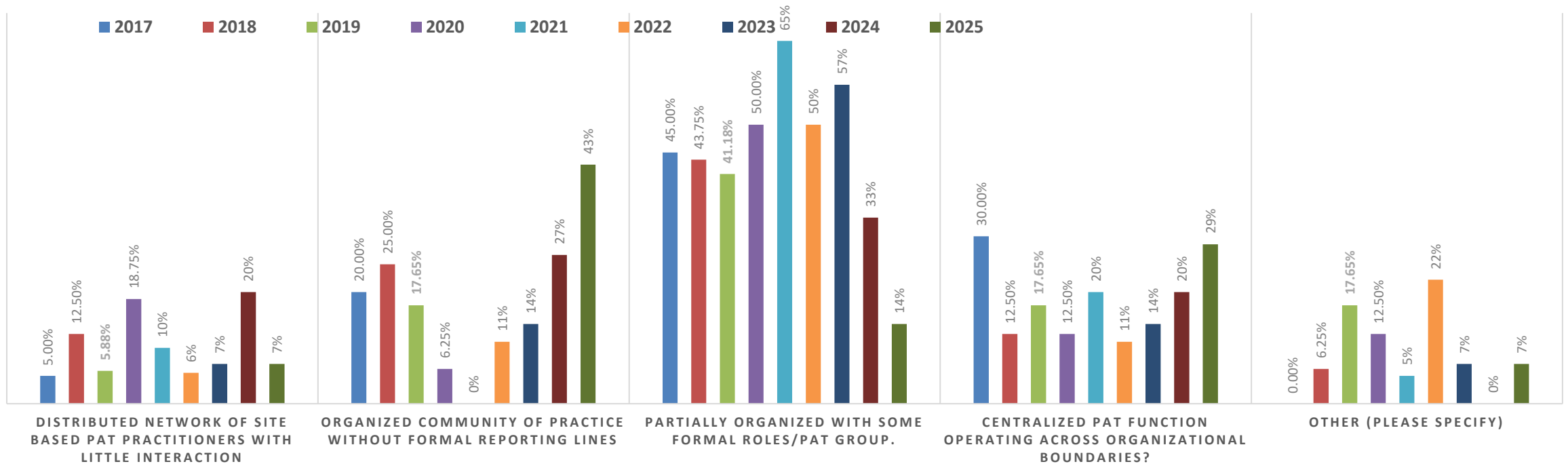
WHAT PRODUCT MODALITIES DOES YOUR COMPANY DELIVER (%)



TEAM ORGANIZATION

This year increase in organized CoP and centralized PAT function working across boundaries

WHICH STATEMENT BEST REPRESENTS HOW YOUR PAT PEOPLE ARE ORGANIZED?



Other setup:

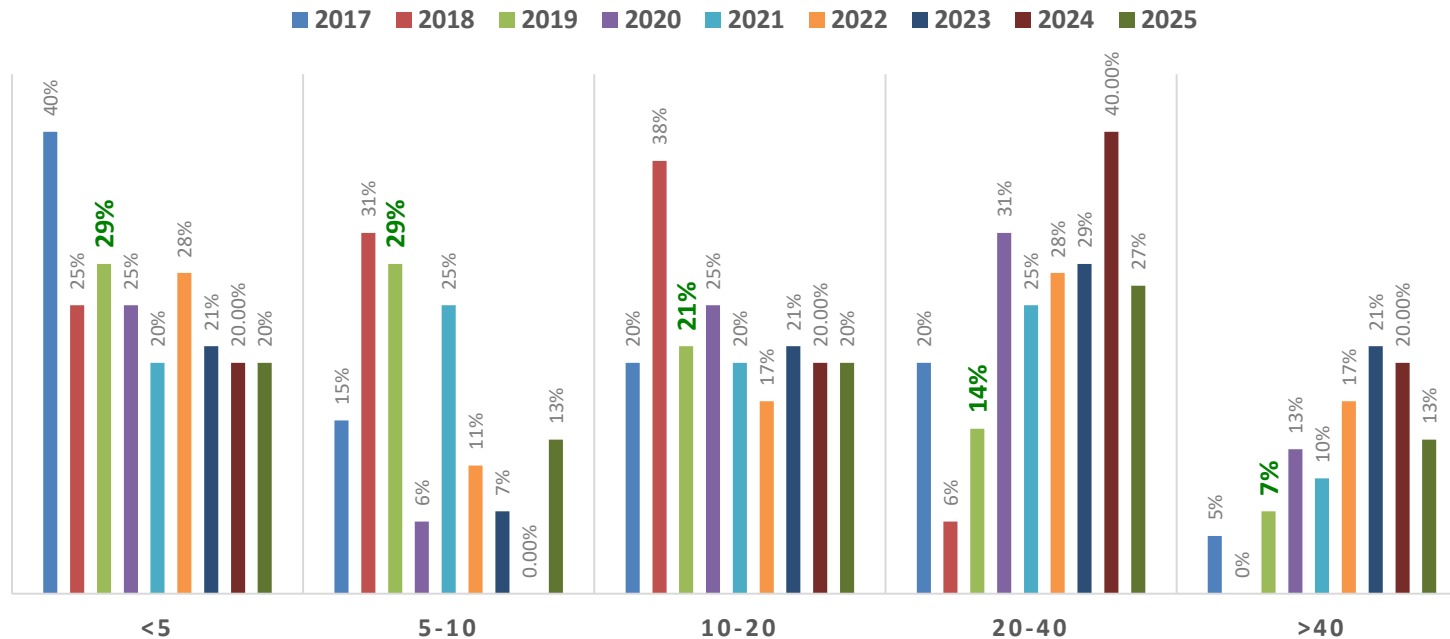
- Combination of organizational models (Partially organized with CoP elements)



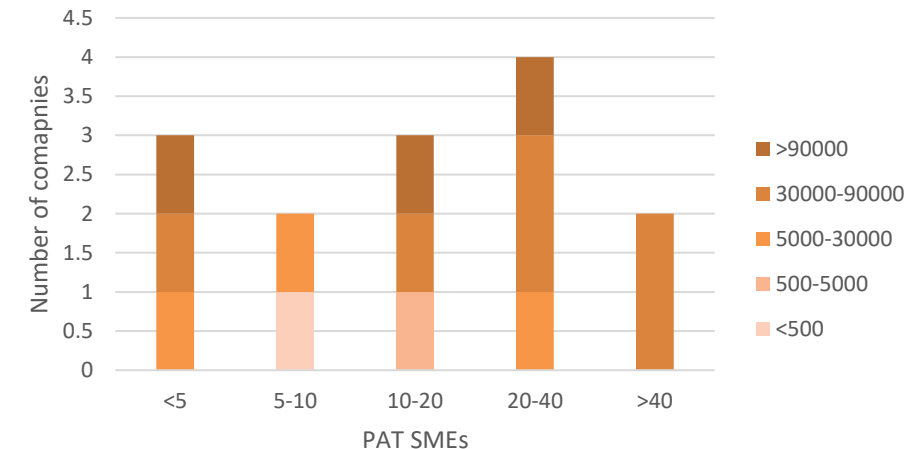
TEAM SIZE, FULL TIME

- Wide range of PAT practitioners at different companies
 - Ratio PAT SME / FTE: 0.04%
- Assumption: center of range for number of PAT SMEs divided by center of range of total FTEs per company. >40 taken as 50 SMEs, >90k taken as 100k FTEs.

HOW MANY FULL TIME PAT PRACTITIONERS AT YOUR COMPANY?



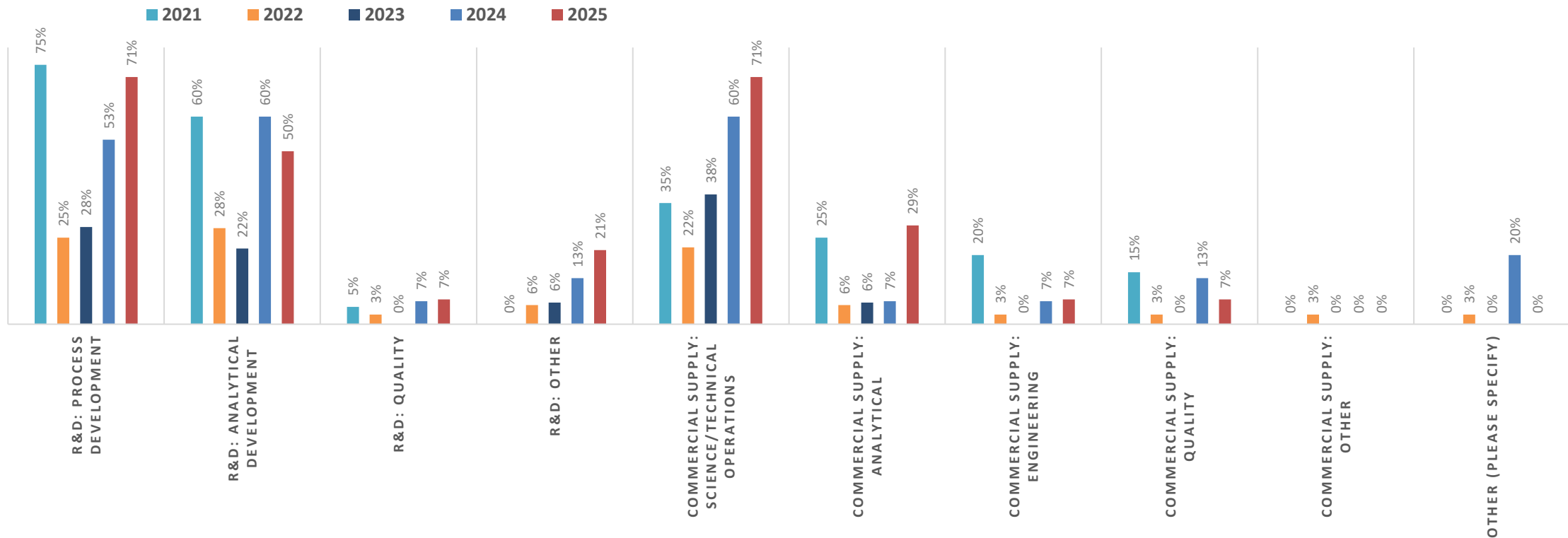
PAT SMEs vs number of employees



PAT IN ORGANIZATION

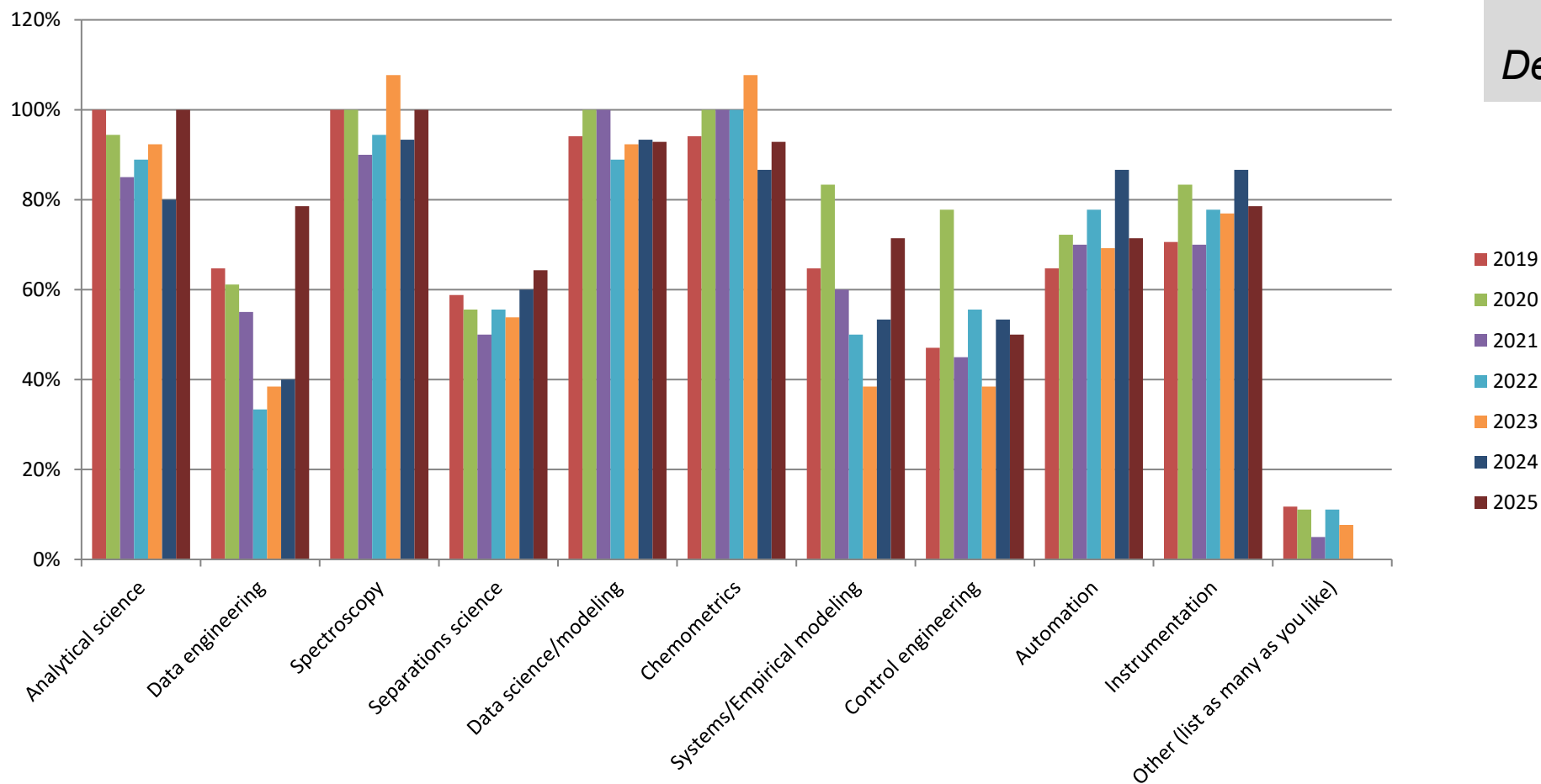
Majority of PAT people organized in development and/or commercial technical operations

WHICH STATEMENT BEST REPRESENTS HOW YOUR PAT PEOPLE ARE ORGANIZED?



CORE COMPETENCIES

What competencies/skills does your organization consider important for performing PAT work? (check all that apply)



Main focus

- Spectroscopy, Analytical Science

Growing focus

- Data engineering
- Systems/Empirical Modeling

Decreasing trend?

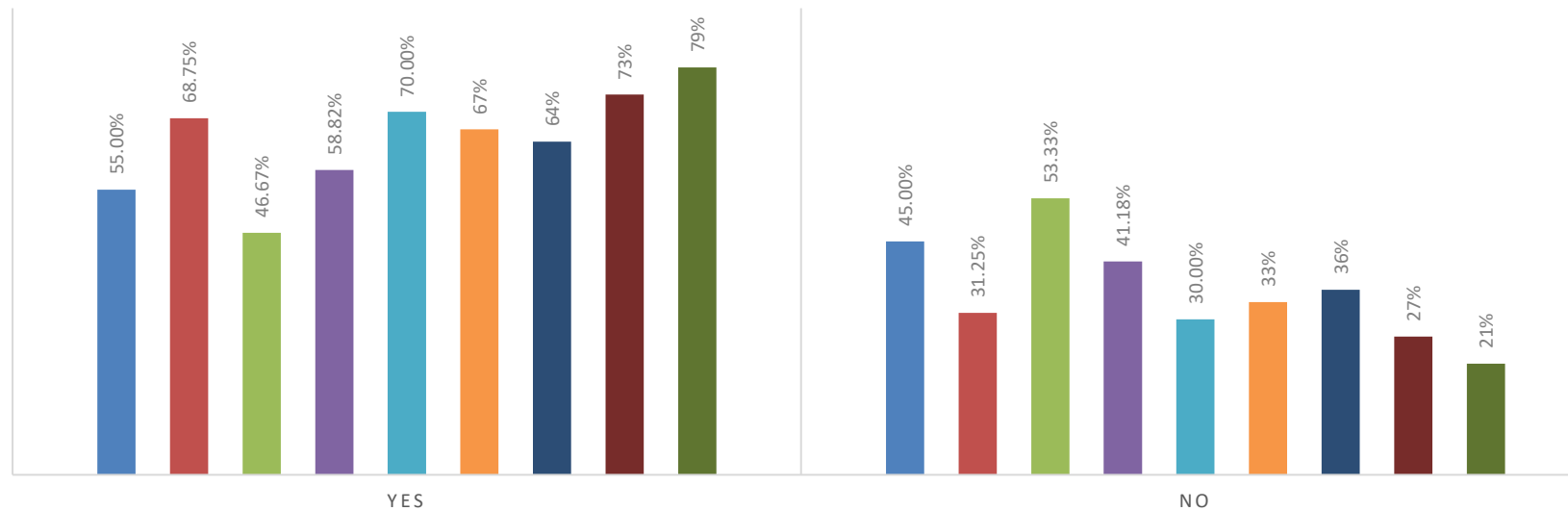


PAT STRATEGY

In last 5 years, appears trend toward formal PAT strategy

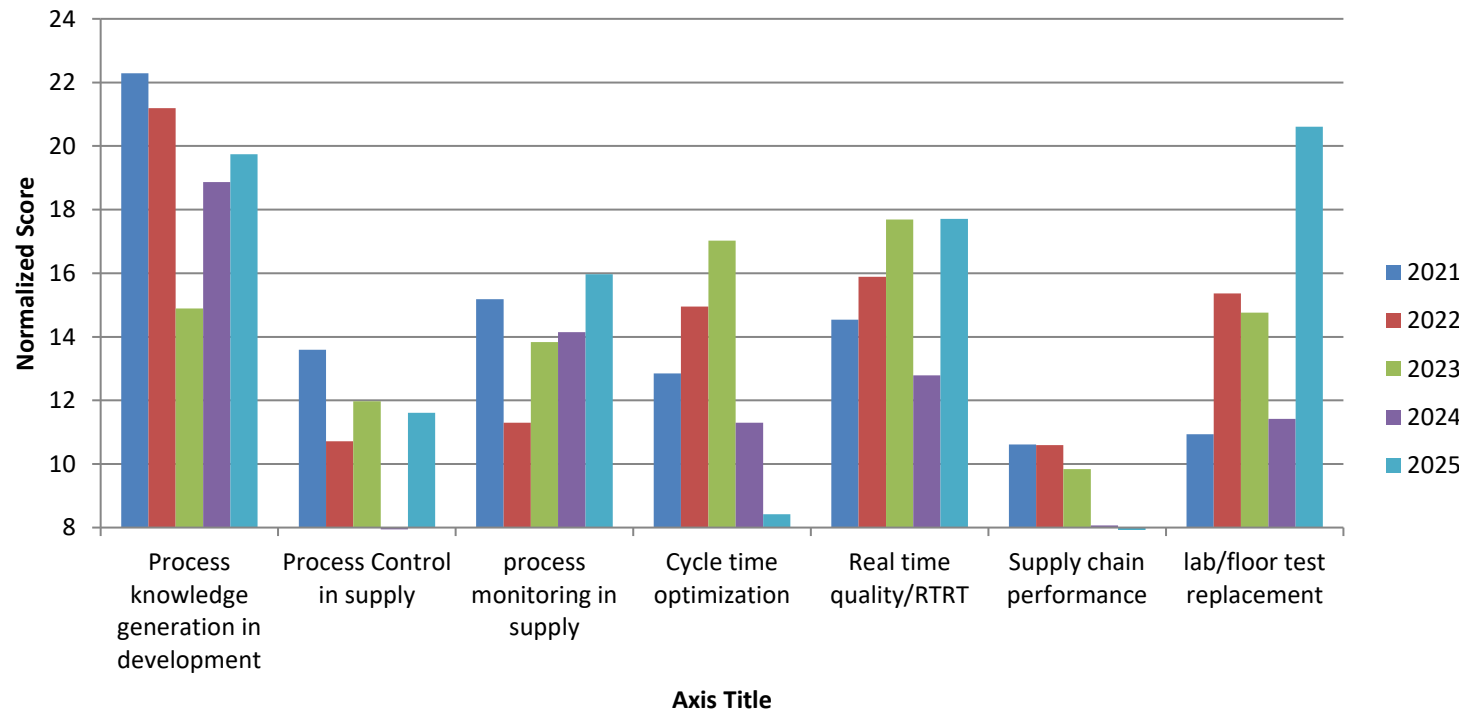
DOES YOUR COMPANY HAVE A FORMAL PAT APPROACH/STRATEGY?

■ 2017 ■ 2018 ■ 2019 ■ 2020 ■ 2021 ■ 2022 ■ 2023 ■ 2024 ■ 2025



PRIMARY DRIVERS

What are the primary drivers of value proposition for PAT at your company?



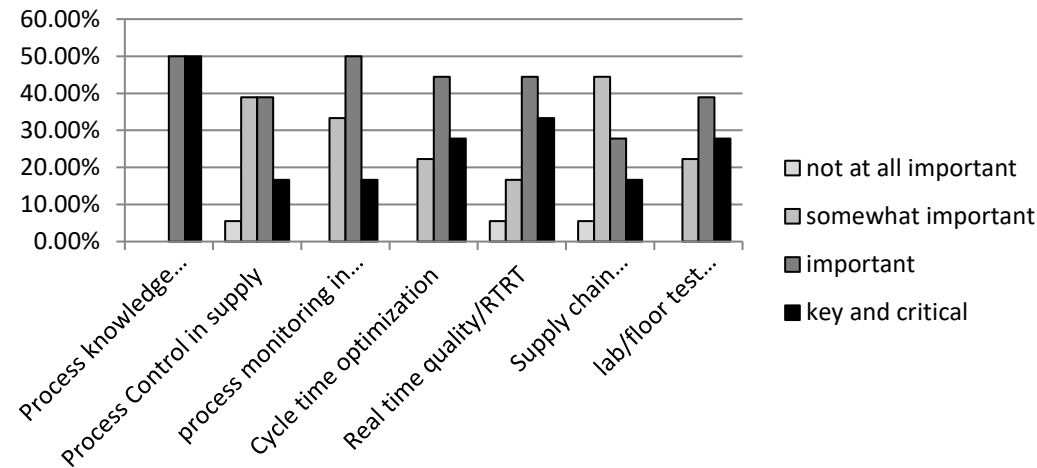
- Main drivers remain process monitoring, process knowledge generation in development
- Cycle time optimization decreasing
- RTRT and lab/floor test replacement saw a surge this year
- Supply chain performance less in focus

calculated score [Rating x Votes, corrected for missed votes and normalized] to allow for year-on-year comparison

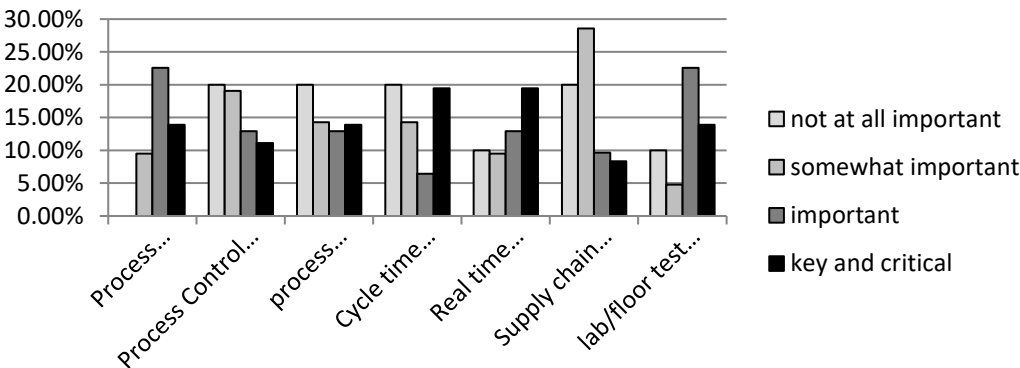


PRIMARY DRIVERS

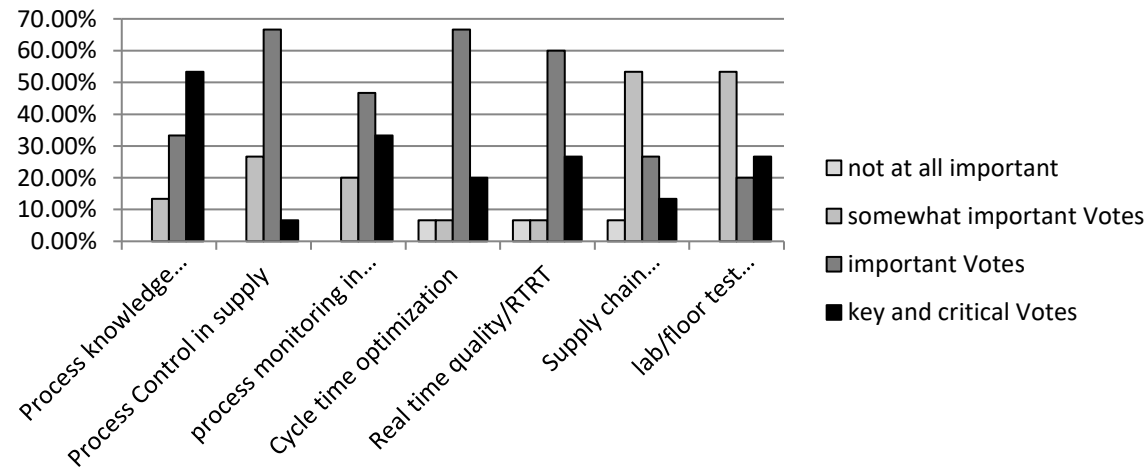
What are the primary drivers of value proposition for PAT at your company? (2022)



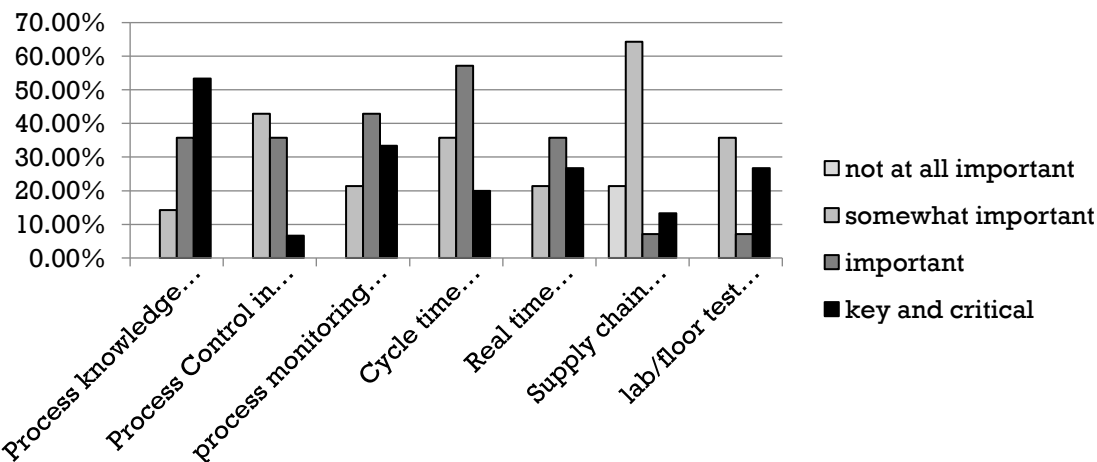
What are the primary drivers of value proposition for PAT at your company? (2023)



What are the primary drivers of value proposition for PAT at your company? (2024)



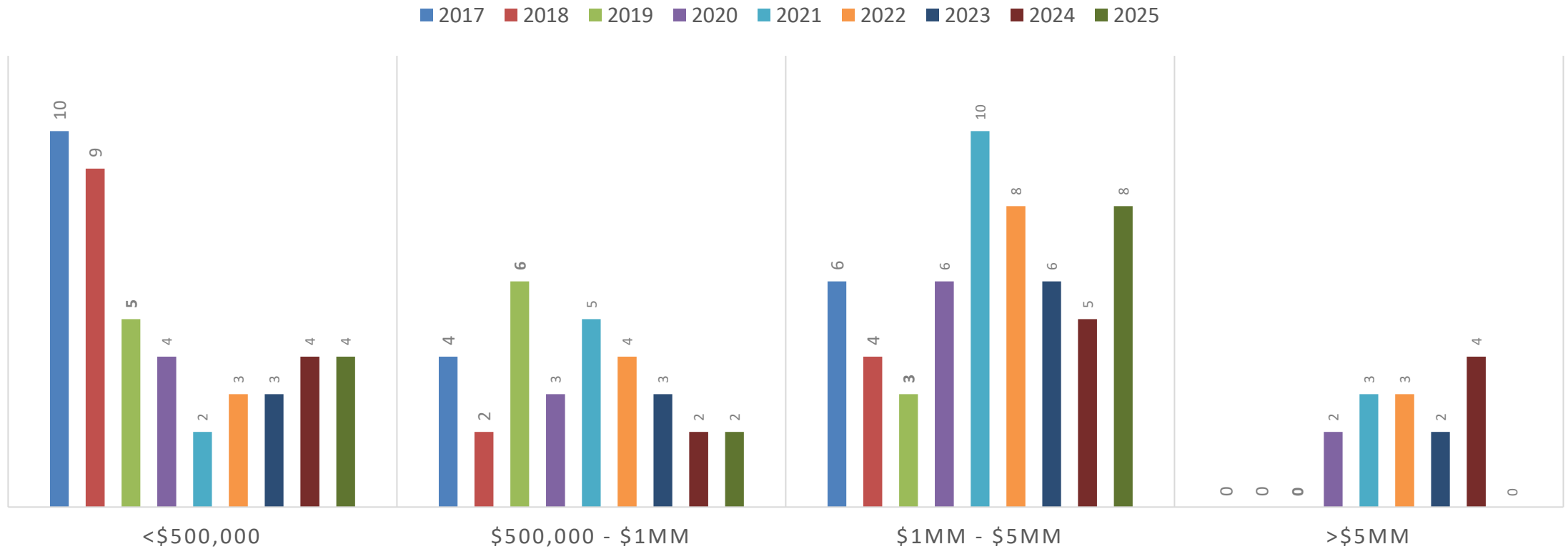
What are the primary drivers of value proposition for PAT at your company? (2025)



ANNUAL INVESTMENT

Investment level fairly consistent

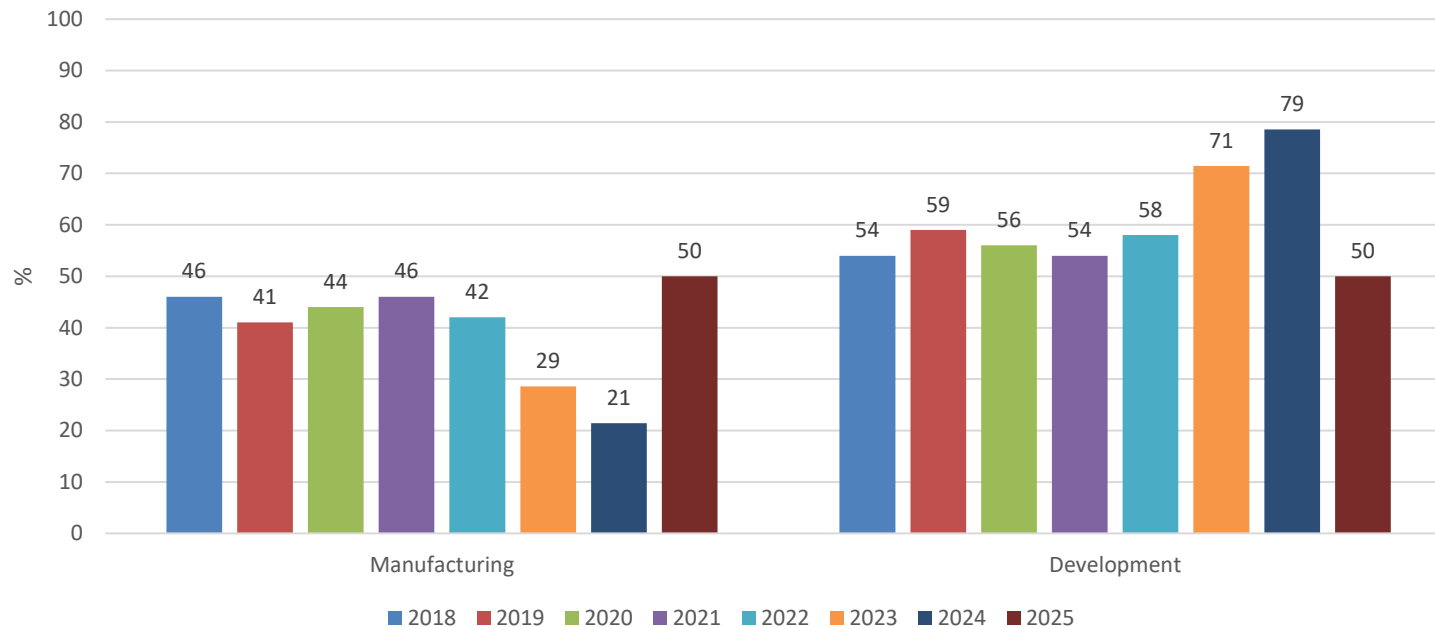
WHAT IS YOUR LEVEL OF ANNUAL TECHNOLOGY INVESTMENT IN PAT?



SPLIT BETWEEN MANUFACTURE VS DEVELOPMENT

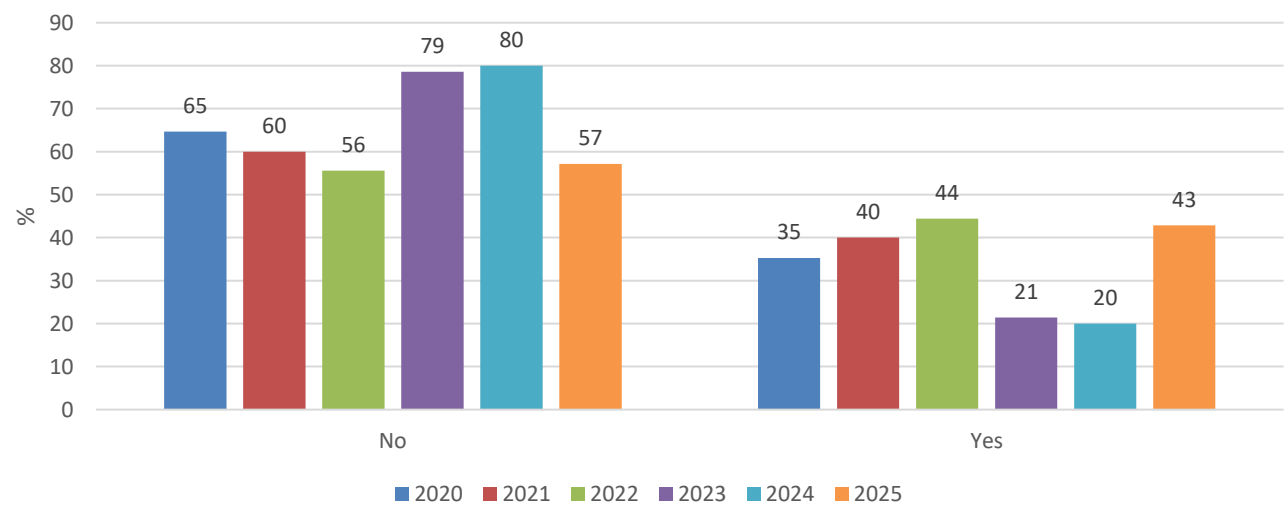
What is the split in PAT Resources in commercial manufacturing relative to that made in development
(in percent)

- See a change in 2025 to a more even split between commercial manufacturing and development



DO YOU OUTSOURCE ANY/PART OF YOUR PAT ACTIVITIES

Do you outsource any part of your PAT project work?

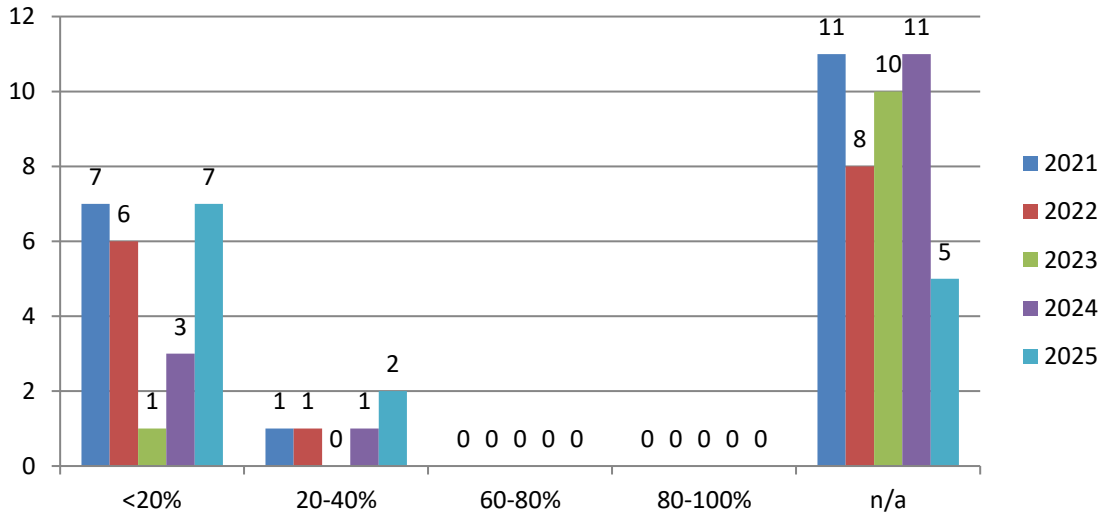


Comparison YOY, percent outsourced

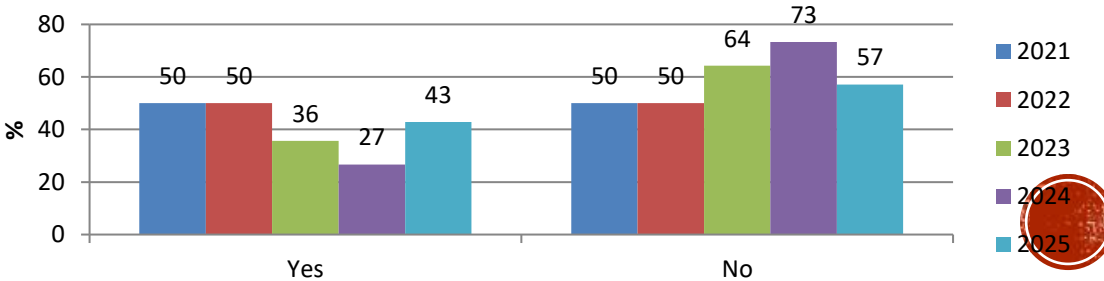
2025: 43%
2024: 20%
2023: 21%
2022: 44%
2021: 40%
2020: 35%
2019: 43%
2018: 0%
2017: 25%

43% of companies request CRO/CMO to implement PAT as part of their core process work, in contrast to 20% last year

If yes - what percentage of PAT work is outsourced?

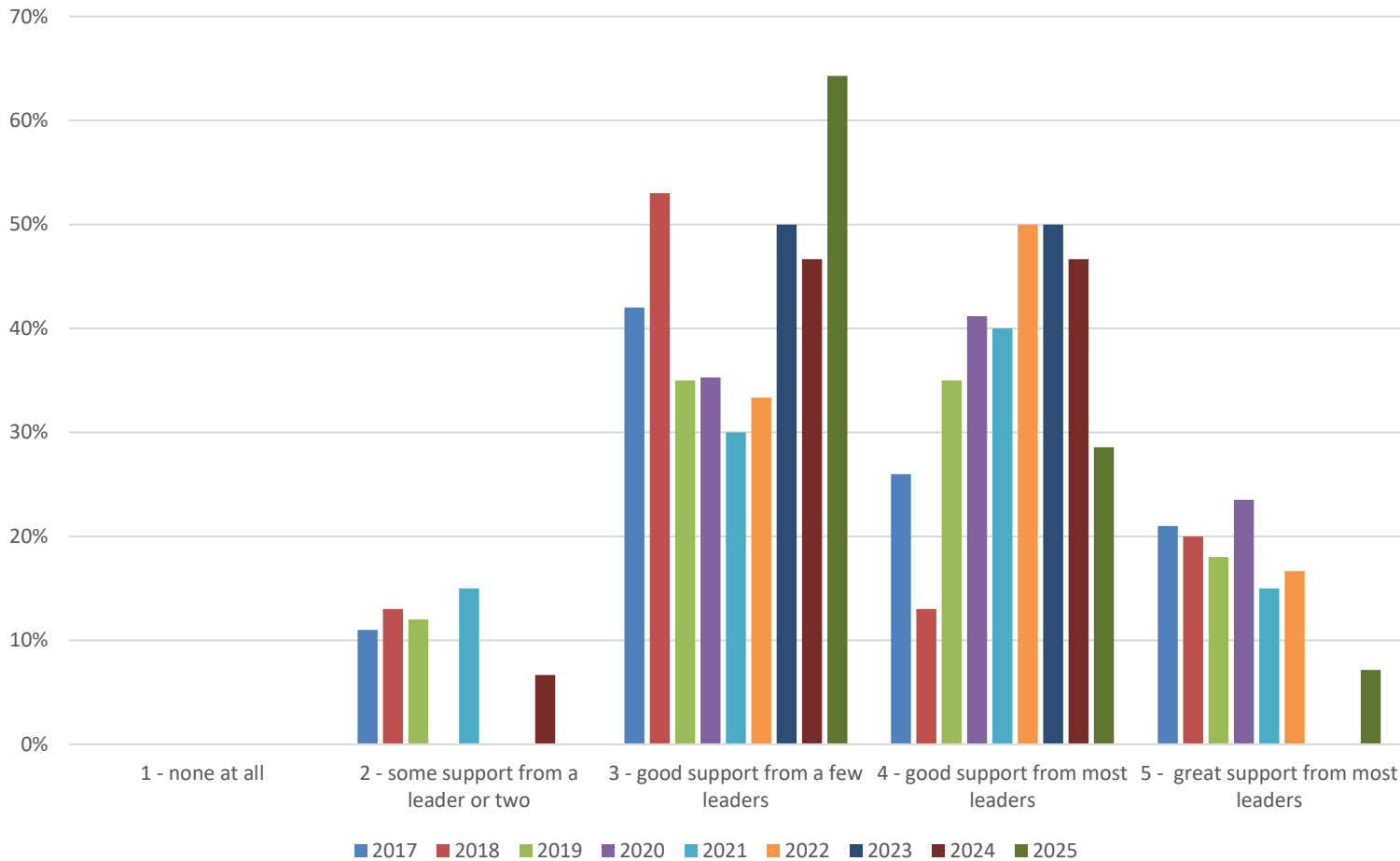


Does your firm request of CRO/CMO partner to implement PAT applications as part of the core process work?



LEADERSHIP COMMITMENT

Level of Commitment from executive leaders



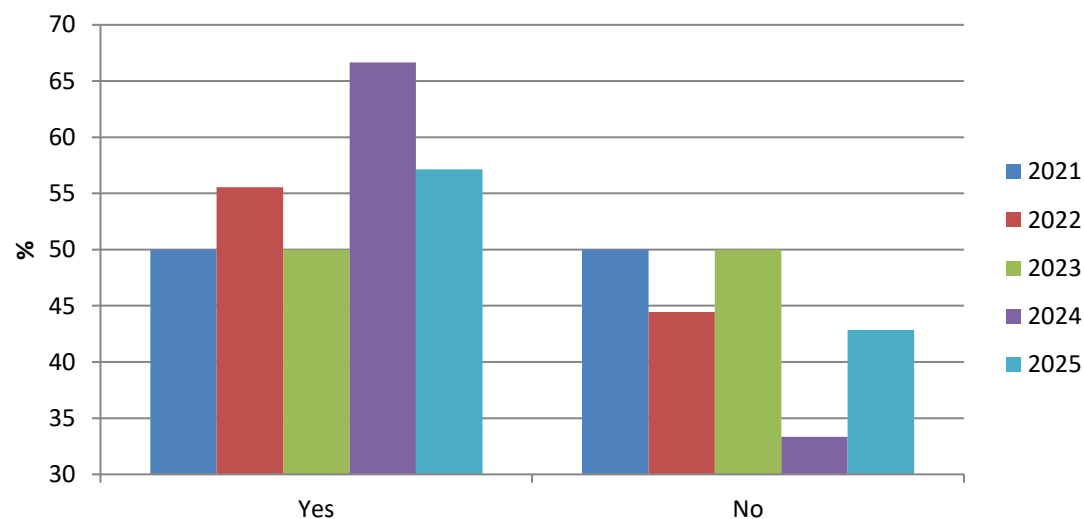
Most companies have good support from a few or most leaders

In 2023 and 2024, no company voted “5 - great support from most leaders”, down from 17% in 2022 – see one company rate 5 in 2025

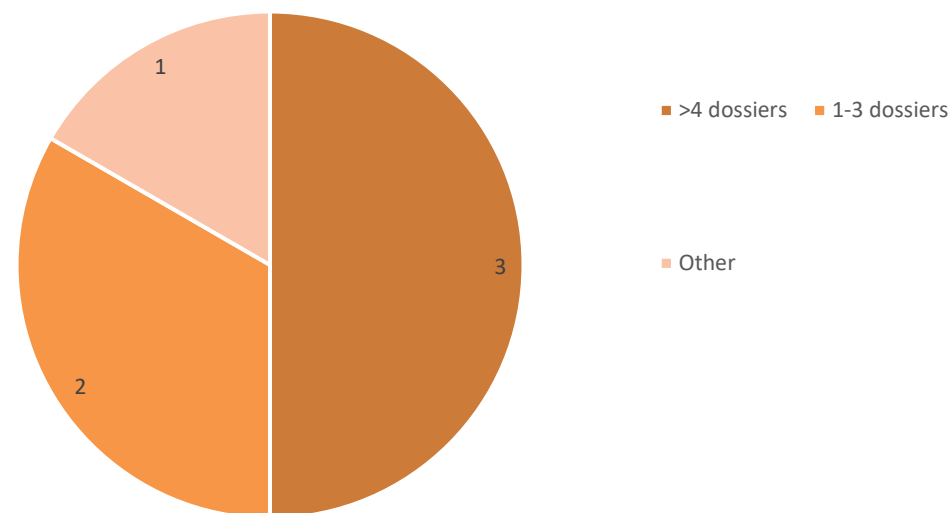


HAVE YOU FILED PAT METHODS IN REGULATORY SUBMISSIONS?

Have you filed PAT in regulatory submissions (NDA/BLA/PAS, etc)?



Have you filed PAT in regulatory submissions (NDA/BLA/PAS, etc)? If yes how many approved?



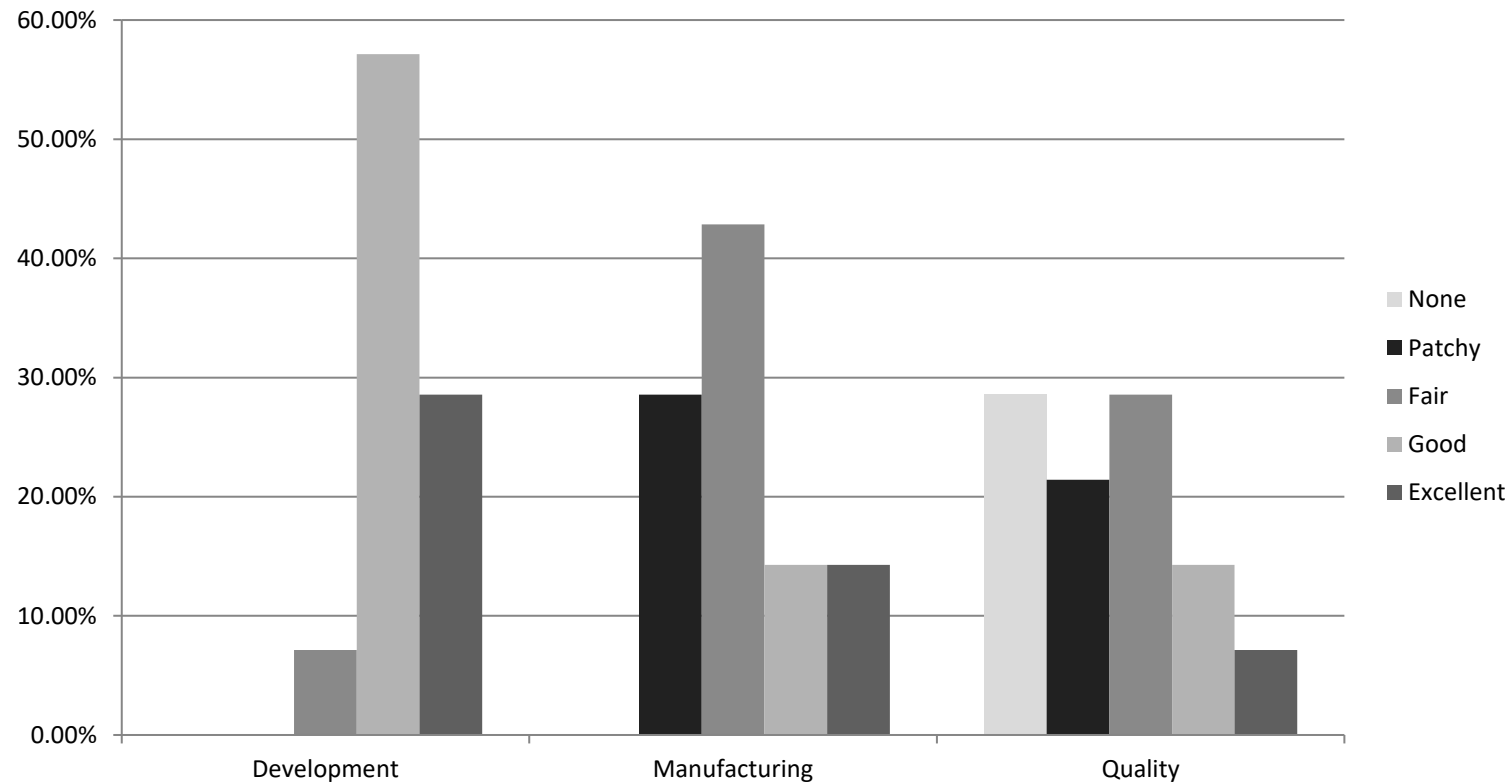
From 2023 and 2024

- 3 companies have between 1-3 dossiers with PAT
- 3 companies have 4-6 dossiers with PAT
- 1 company has >10 dossier with PAT



HOW MUCH PAT ADOPTION / INTEGRATION IN QUALITY, DEVELOPMENT, MANUFACTURING

What is the level of PAT adoption and integration within your development, manufacturing and quality organizations?

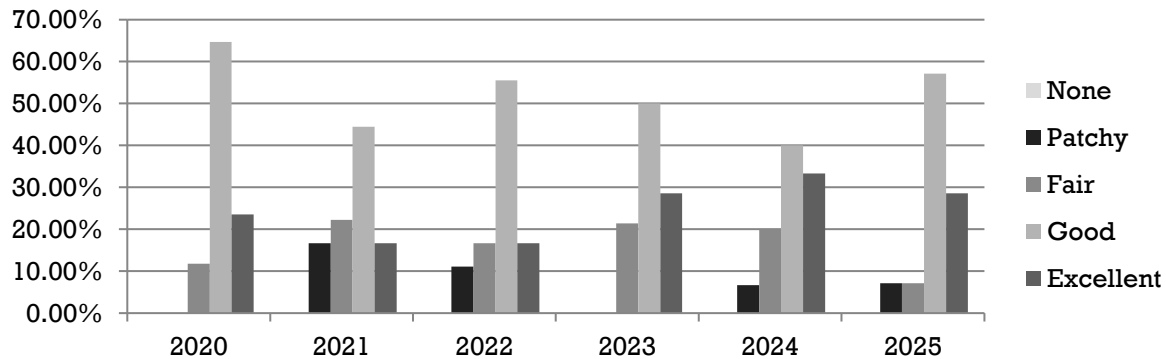


- Good to excellent adoption in Development
- Good to fair in Manufacturing
- Quality has lowest level of adoption

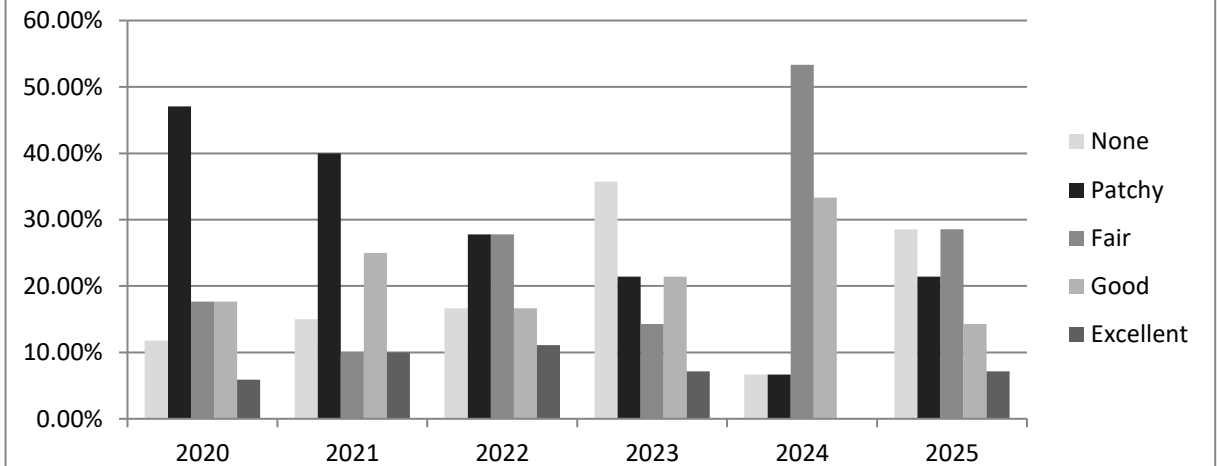


HOW MUCH PAT ADOPTION / INTEGRATION IN QUALITY, DEVELOPMENT, MANUFACTURING

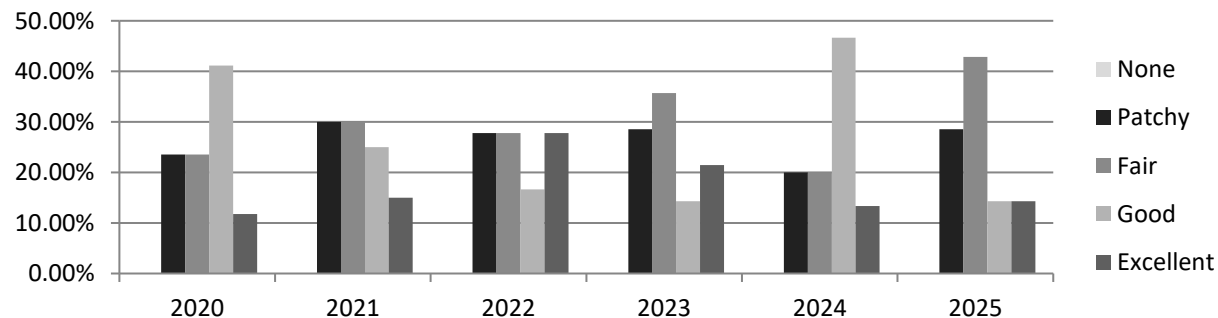
What is the level of PAT adoption and integration within your **Development** organization?



What is the level of PAT adoption and integration within **Quality** organization?



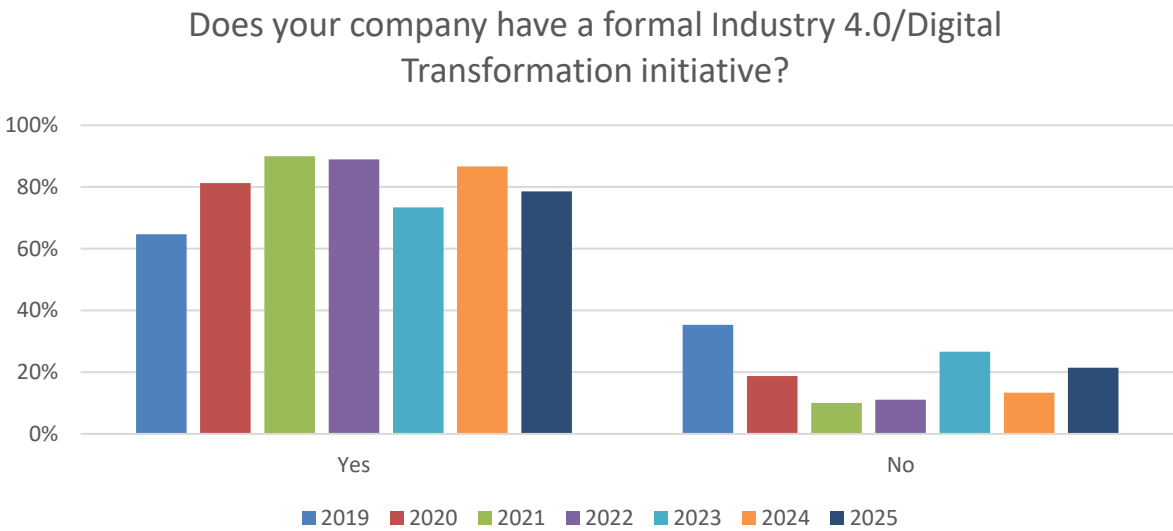
What is the level of PAT adoption and integration within your **Manufacturing** organization?



General trend moving toward fair/good/excellent in development and quality. More consistent in manufacturing.

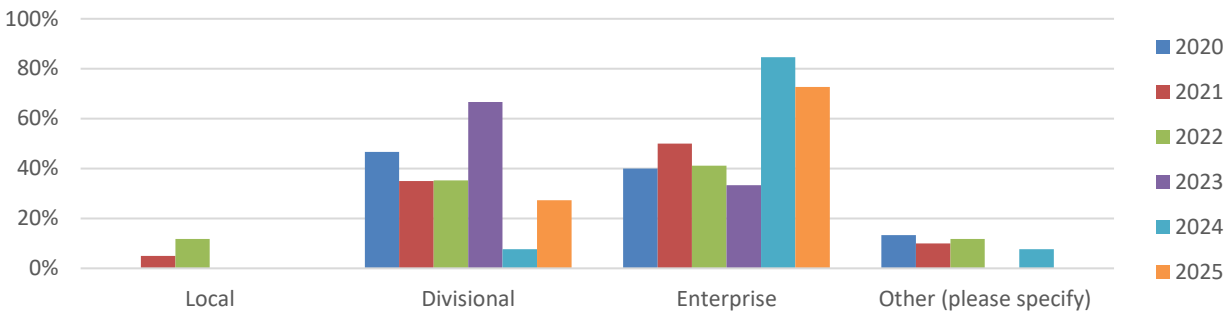


INDUSTRY 4.0

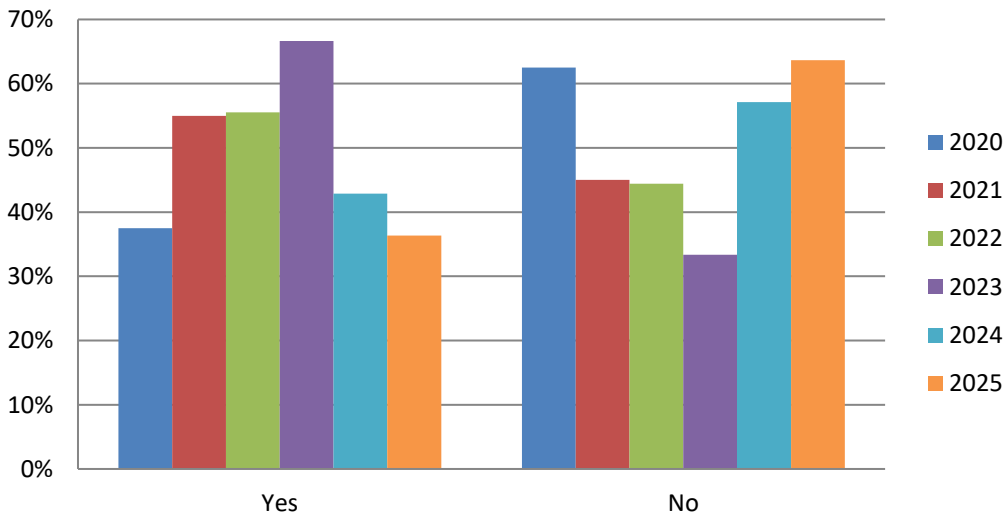


Some decrease from last year, 79% companies have a formal Digital Transformation program

If yes, is the strategy at a local, divisional, or enterprise level?



Is PAT explicitly an element of the strategy?



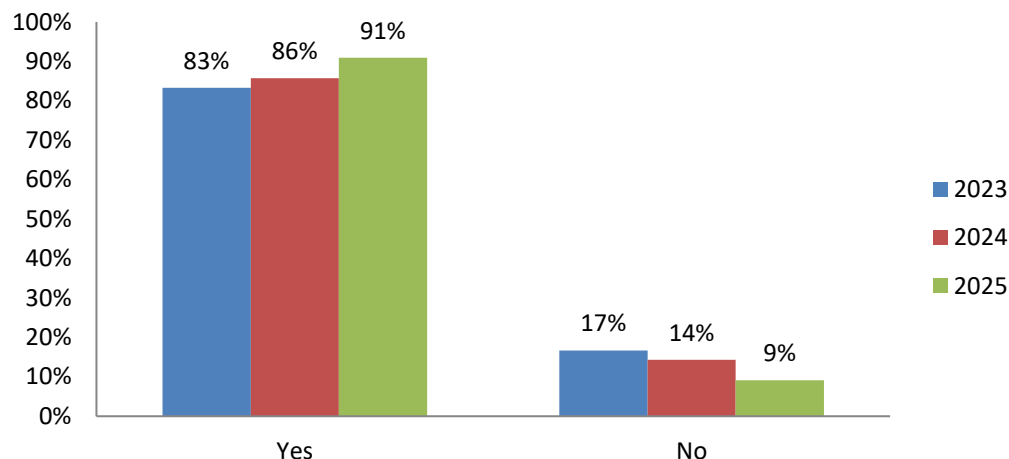
2024 & 2025 trend toward not explicitly including PAT in strategy



IN-SILICO MODELING

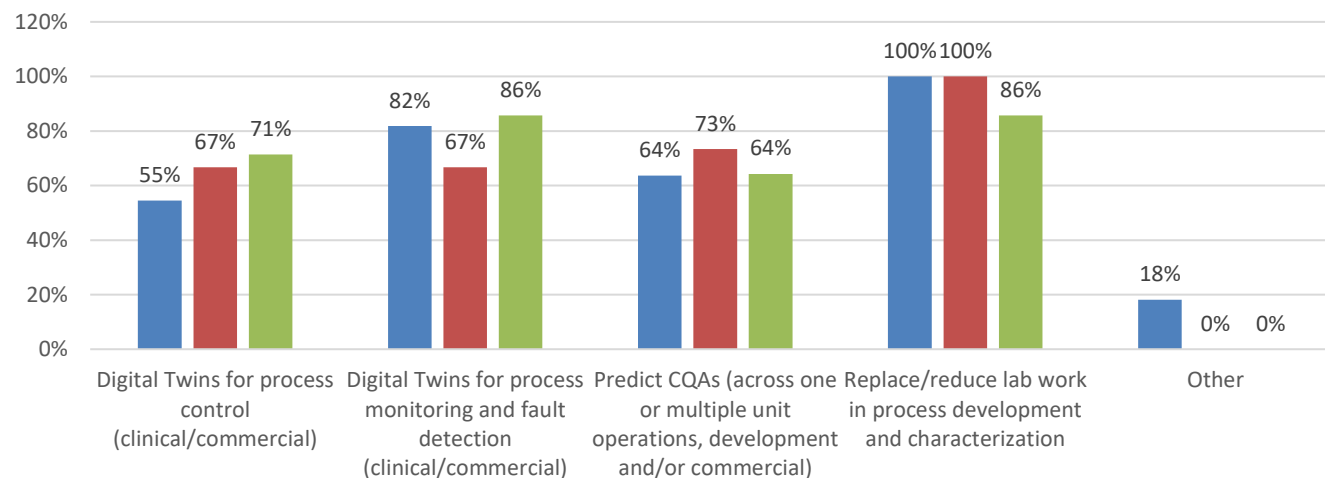
(NEW QUESTIONS 2023)

Is in-silico modeling part of your Industry 4.0 / Digital Transformation strategy?



- Modeling essential part of Digital Transformation strategy for most companies
- Reduction of lab work in development is key driver
- Increase in digital twins for process monitoring/fault detection

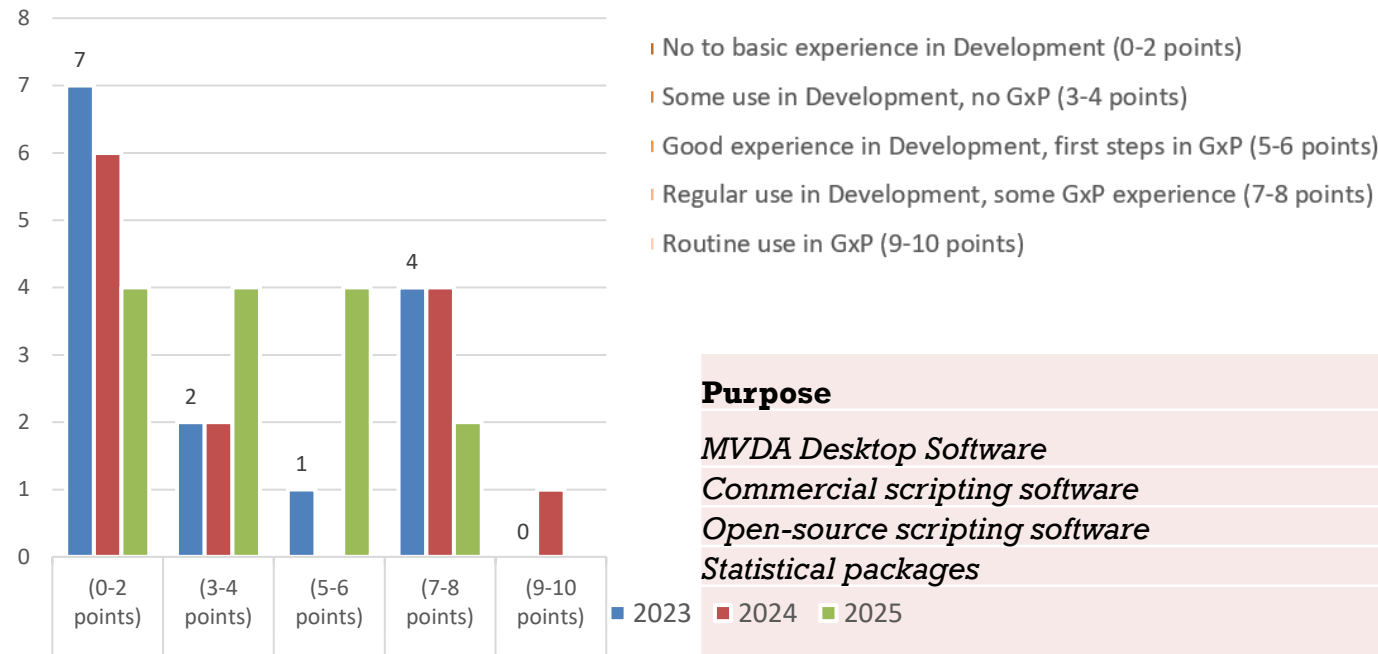
What goals does your company pursue with in-silico modeling?



MODELING SOFTWARE

(NEW QUESTIONS 2023)

How would you rate the readiness and experience of your company regarding the use of open source and/or cloud based tools in GxP applications? (think Python, R, ChatGPT, ...)



Open-source adoption

- Most companies have experimented with open-source modeling software

Software

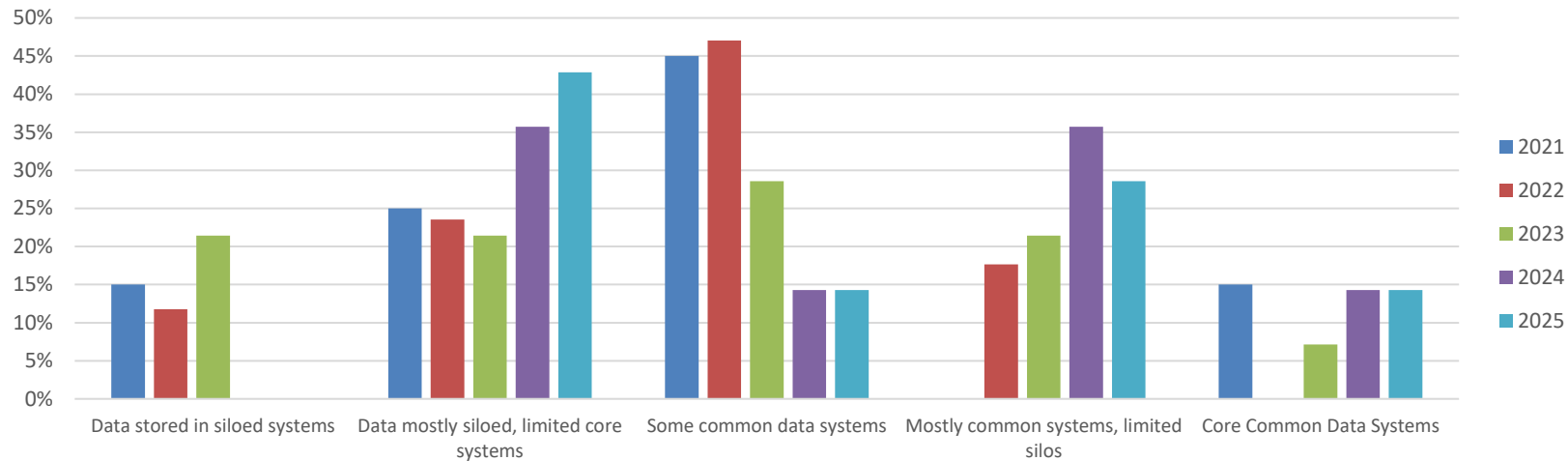
- Wide range of different tools
- Commercial packages dominate
- Increase in AI packages and use since last year

Purpose	Software Tool
MVDA Desktop Software	SIMCA, PLS Toolbox, Unscrambler
Commercial scripting software	Matlab, gPROMs
Open-source scripting software	Python, R, R Shiny
Statistical packages	JMP
Special purpose	GoSilico, Dynochem,
Commercial process modeling	PharmaMV, DataHow
AI	Open AI, Copilot, Databricks, NVIDIA, internal AI
	In house solutions



DATA MANAGEMENT — IN DEVELOPMENT & COMMERCIAL

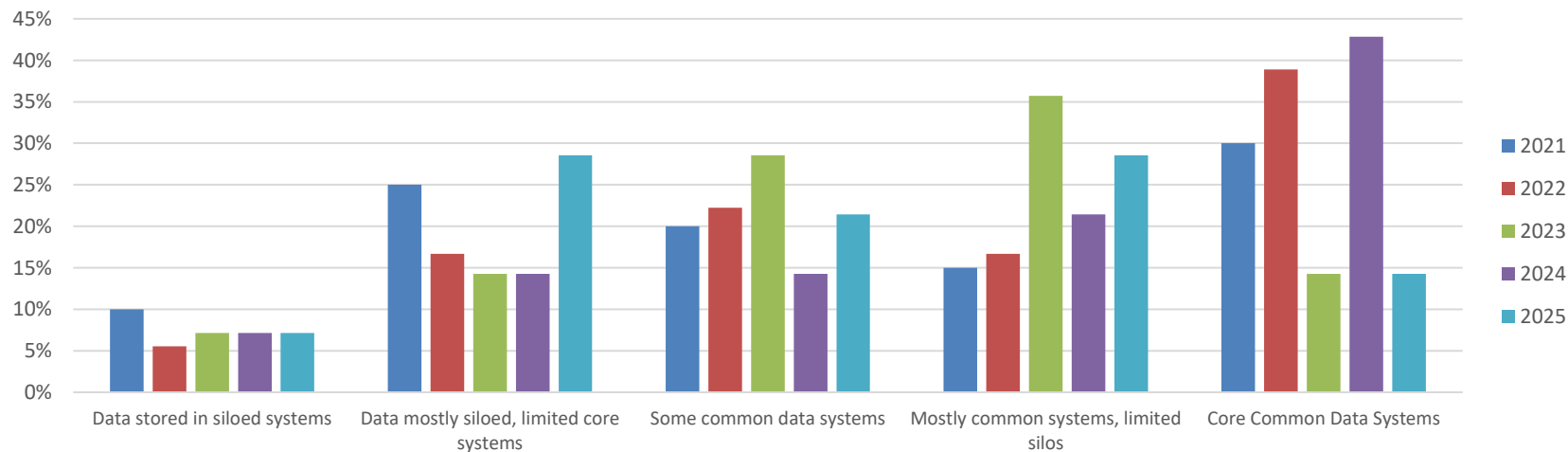
How is **development** data (includes PAT) managed in your company?



In Development

- Some inconsistency YoY, likely due to different company participation

How is commercial data (includes PAT) managed in your company?



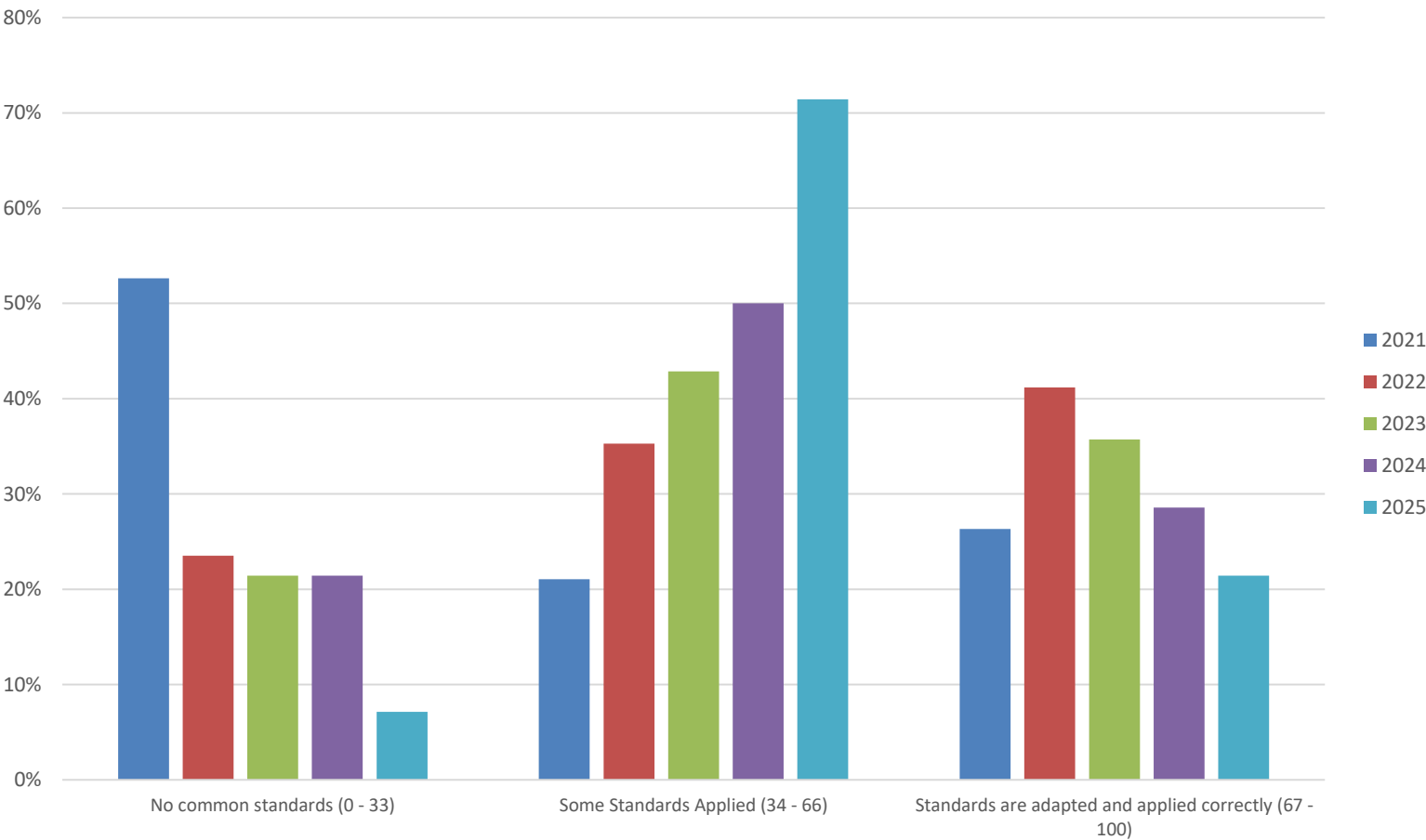
In Commercial – higher maturity

- Consistent YoY with commercial generally having higher data maturity than development
- Decrease in Core Common data systems in 2024 compared to 2024



DATA STANDARDS – MATURITY

How are data standards applied in your company?



Clear improvement towards data standards



CHALLENGES

2025

- Resources: instrument cost, FTE (limited skill sets, bandwidth, experience)
- Sponsorship, organizational alignment
- Externalization to CMOs
- Business case development, value driver
- Regulatory/filing risks, perceptions of manufacturing risks
- Technical complexity (including retrofitting equipment for PAT capability)
- Vendor reliability: instrument cost, instrument robustness
- Modeling data constraints relating to GMP validation
- Lifecycle/change management
- Culture
- Shifting from development to manufacturing
- Urgent/shifting project timelines

Note:

- Complete list in Back-up

2024

- Resource and budgeting challenges (FTEs, Capex)
- Internal business support and Business case development
- Equipment maturity, vendor capability and readiness
- Regulatory challenges
- Business process integration and LCM
- Reluctance to embrace changes
- Lack of skills internally and with CMOs
- General education on PAT concepts
- Visionary leadership support and sponsorship
- Alignment between functions
- Internal risk culture
- GMP readiness of equipment, data modeling, and IT
- Project timelines

2023

- Business process integration and LCM
- Internal business support and Business case development
- Internal risk culture
- Resource and budgeting challenges (FTEs, Capex)
- Equipment maturity, vendor capability and readiness
- IT support, ownership
- Lack of skills internally and with CMOs
- Regulatory challenges
- General education on PAT concepts



ENABLERS

2025

- Process robustness
- Productivity increases
- Speed to release, increasingly reducing drug development timelines requiring need for QA and consistency
- Digital
- Strong leadership support
- Alignment between R&D and commercial, clear application definition and alignment
- Embedding a culture of PAT so it is routine for all
- Aligning data management and repository
- Resources: budget for equipment and software
- Risk acceptance (top to bottom)
- Scientist passionate about new tech and moving the needle, right skillset
- Regulatory examples/guidance/engagement

Note:

- Complete list in Back-up

2024

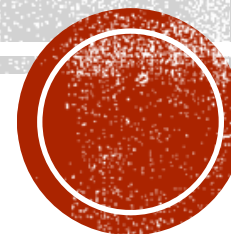
- Visionary leadership support and sponsorship
- Dedicated resources and sufficient funding
- Solid business case via alignment between business organizations
- Required technology and infrastructure in place, including aligned data repositories
- Serious adoption of PAT in organization
- Increased demand for process and asset optimization
- Alignment between R&D and manufacturing
- Regulatory guidance and other learnings

2023

- Visionary leadership support and sponsorship
- Solid business case via alignment between business organizations
- Required technology and infrastructure in place, including aligned data repositories
- Dedicated resources and sufficient funding
- Serious adoption of PAT in organization
- Increased demand for process and asset optimization
- Appetite for non-spectroscopic PAT



BACK-UP



ENABLERS – COMPLETE LIST OF RESPONSES

Respondent	Response
1	Leadership buy-in, Engaged champion consistently building support, strong workforce development
2	QbD, Process monitoring and control
3	desire to deliver faster leads to interest in new tech, passion of scientists and champions, strong past cases demonstrating value proposition
4	management support, expert at manufacturing
5	(1) Modernizing the manufacturing plant and labs has created a lot of opportunity and tail winds to implementing PAT.
6	Tangible success stories (big or small); Good network across supply chain; reliable vendors
7	- Creating standard PAT packages for processes / unit operations
8	process champions, executive champions
9	1. Digital literacy; 2. Stakeholder management; 3. Inter-department collaboration
10	proof of value (monetary or risk related), low risk implementation plan
11	Dedicated SME's, Budgetary resourcing to move technology forward, aligning data management and repositories
12	dedicated headcount and expertise, champions across various levels
13	Support from leadership, collaborations and knowledge-sharing across organization, aligned strategies, business adoption
14	Strong business drive. Senior leadership support.



CHALLENGES – COMPLETE LIST OF RESPONSES

Respondent	Responses
1	Limited mature vendors and vendor ecosystem. Full system / process integration challenges. Specialization/skills required for routine use/interpretation.
2	
3	cultural barrier/mindset - value proposition v. time and requirements for deployment, initial financial burden for new technology when ROI unclear, technology robustness
4	low dose, new material variable at late phase
5	(1) Expectation that PAT has to be right the first time. If there is any wavering then it gets cut immediately. (2) Who is going to own it, Quality org or Tech ops? (3) Manufacturing plants are hesitant to accept and support PAT because it is unfamiliar to them. (4) The value proposition is seen differently between the manufacturing site and the development teams.
6	Harmonization of regulatory expectation; Supply chain strategy; Conservative mindset of doing things
7	1) Lack of PAT awareness within the company prevents: a) management from committing with investment (i.e. balance between benefits and effort of implementing PAT) b) internal clients to adhere to PAT when model lifecycle is a reality c) larger penetration of PAT when users are not aware where / when can benefit from deploying PAT // 2) Dependency on client interest for implementation of PAT (CDMO perspective)
8	Trust, application data, client adoption
9	1. Harmonized goals and strategy between departments, with key technologies identified and roadmapped; 2. Vision for use in commercial spaces
10	Proof of value, risk to GMP operations, data to scale
11	Budget Constraints, FTE Challenges, Organizational Alignment
12	translation of business value from R&D to commercial, willingness to adopt/change managem
13	Changes of ways of working, initial deployment cost, GMP deployment, infrastructure, FTE (PAT SMEs in manufacturing), lack of standardization/platform, hardware reliability
14	Lack of knowledge and experience among business partners. Competing priorities for deployment.

