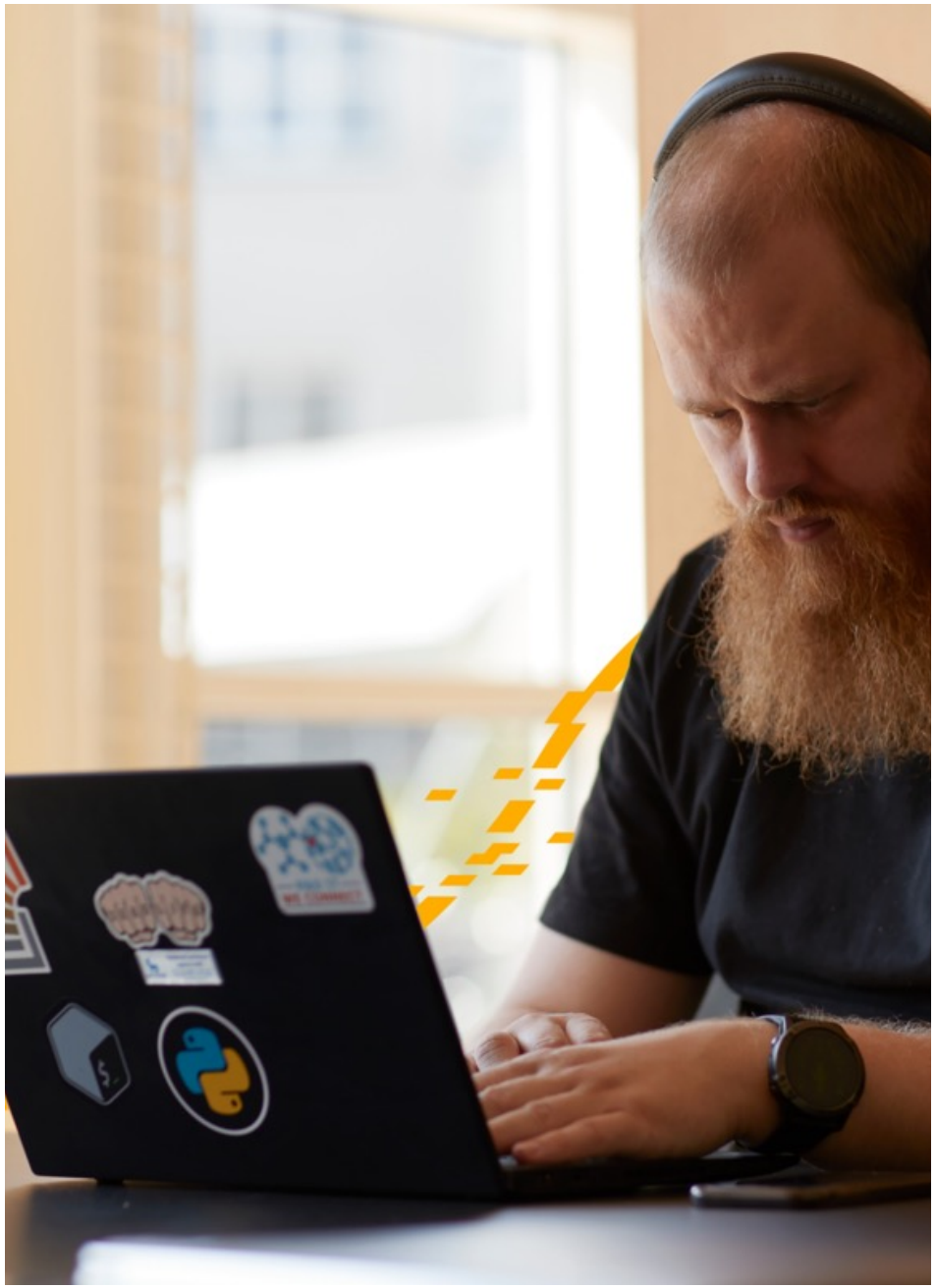

Automation in Biostatistics at Novo Nordisk

LI05

Matthew Phelps

Statistical Programing Specialist, Novo Nordisk A/S

November 2022

Views and opinions expressed are those of the speaker and not necessarily Novo Nordisk.

Agenda

1. Why automation?
2. What is automation?
3. How do we work?
4. What do we do?

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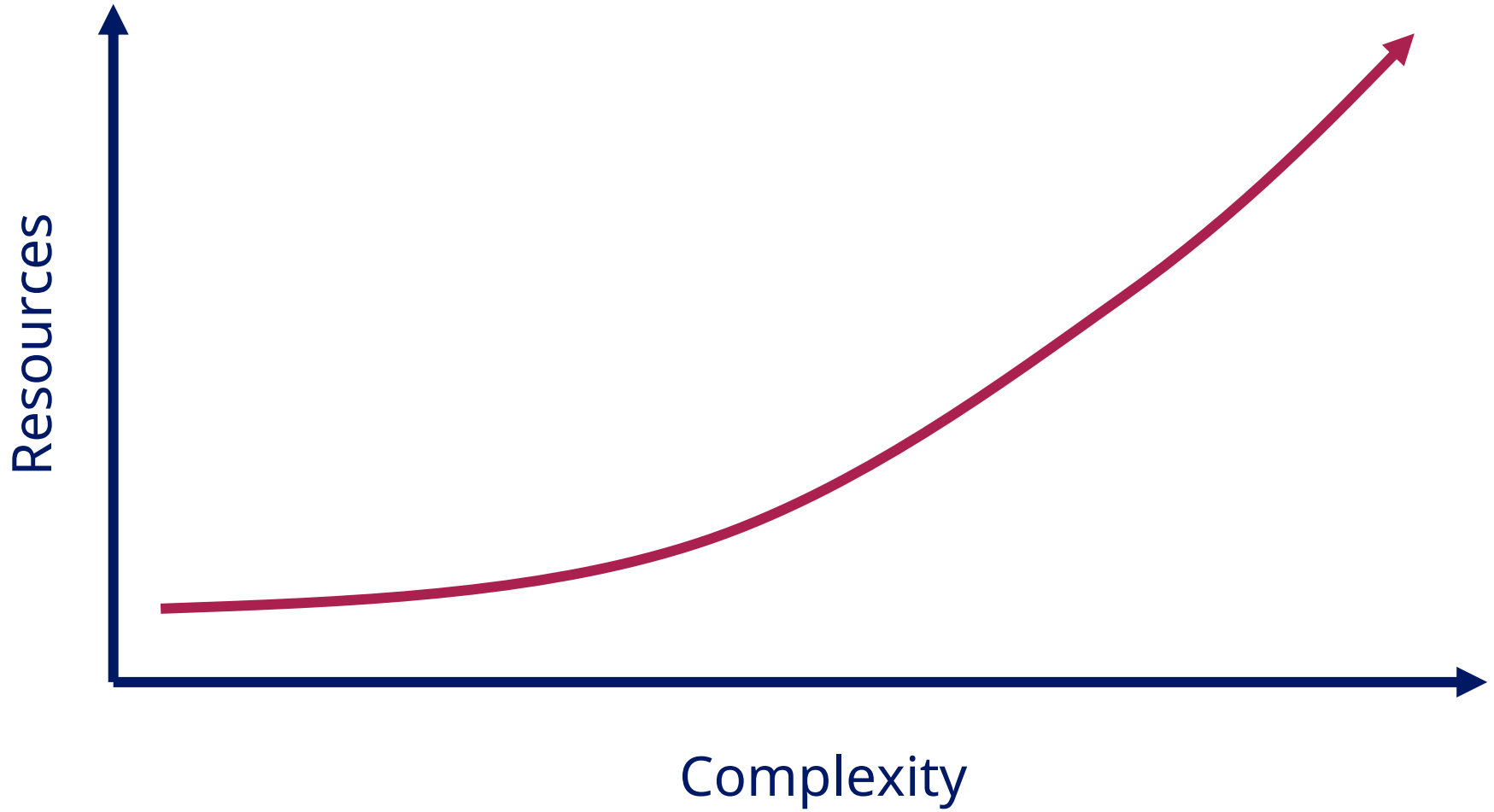
Increasing complexity



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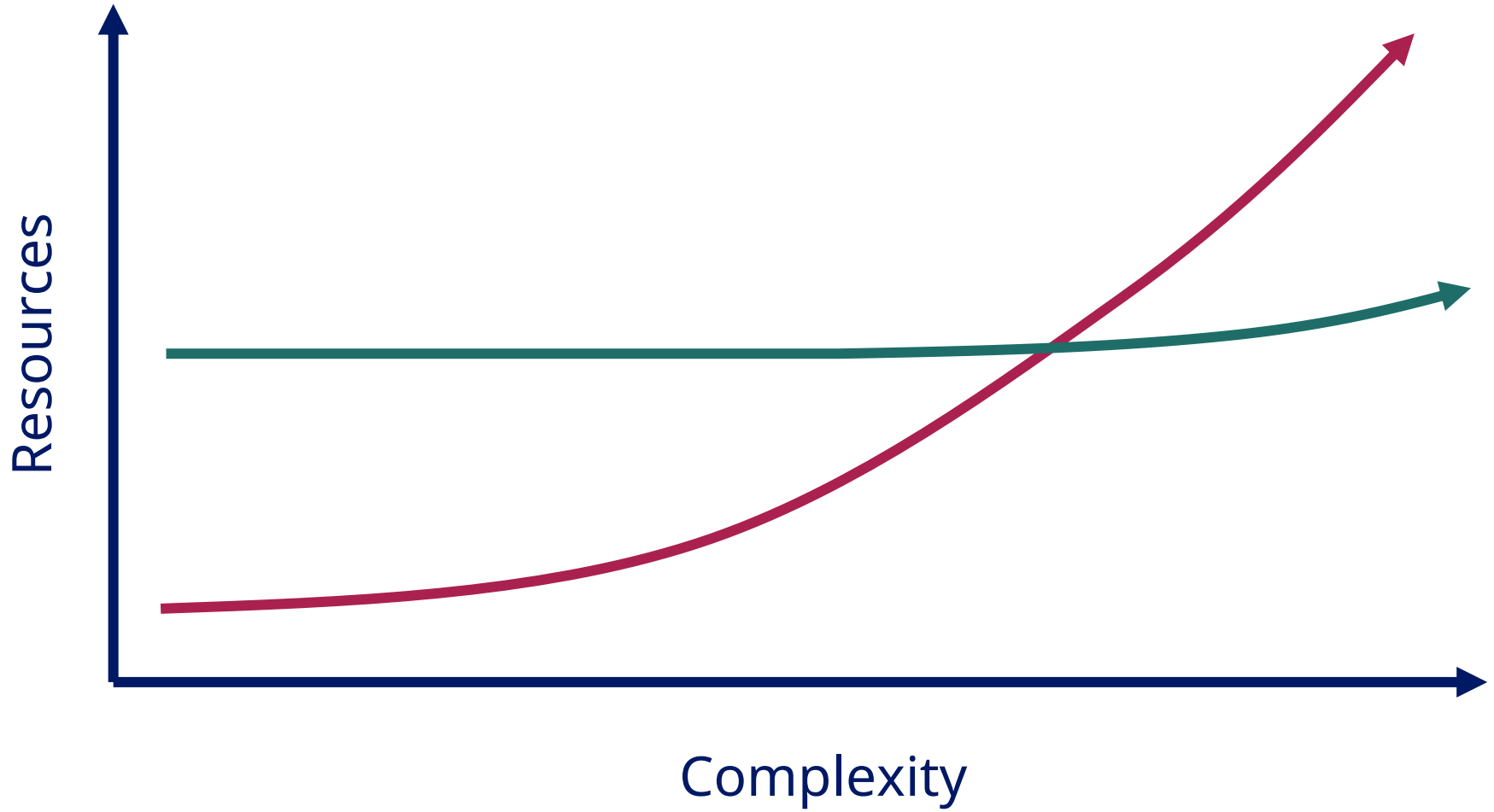

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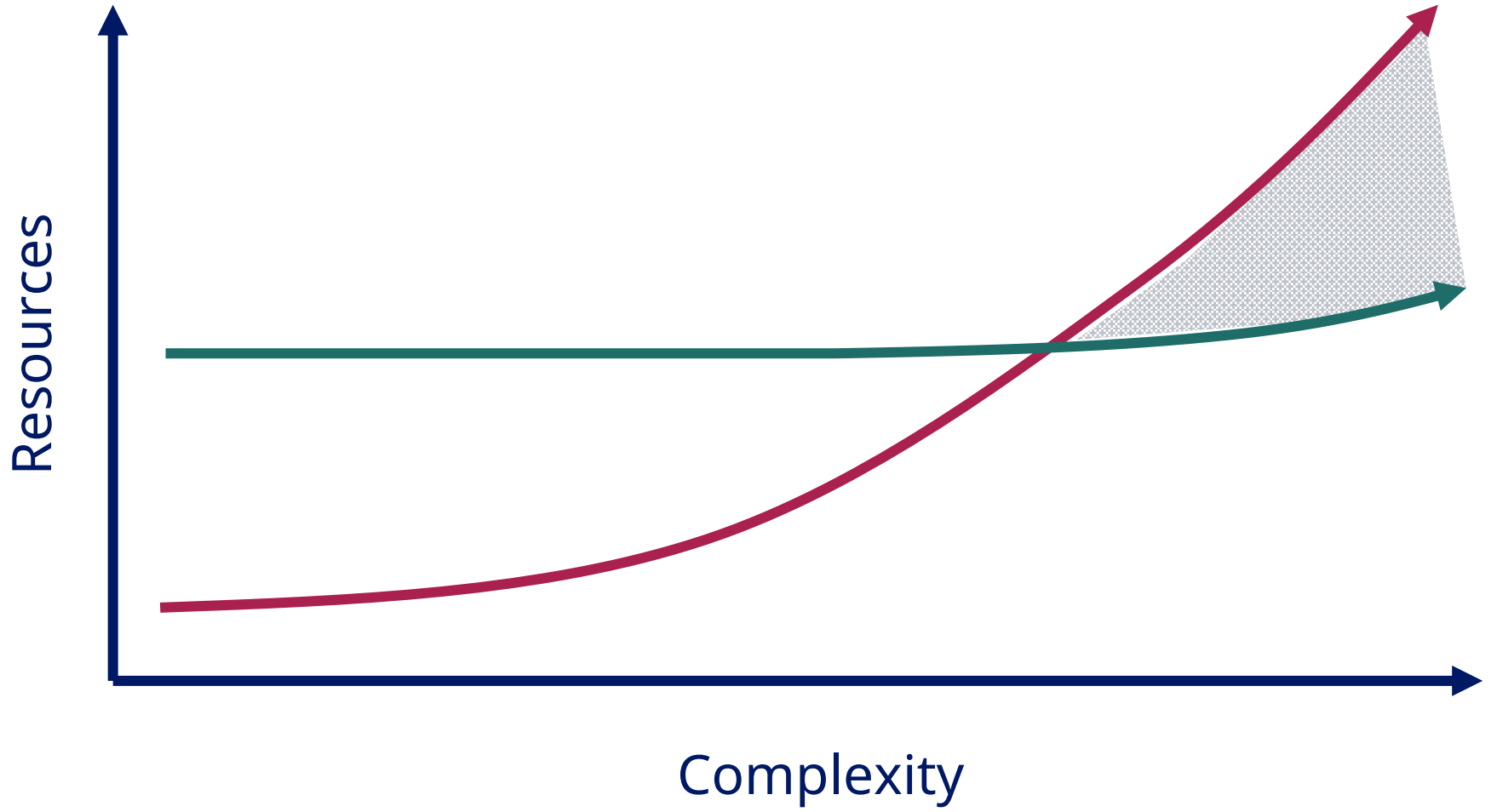

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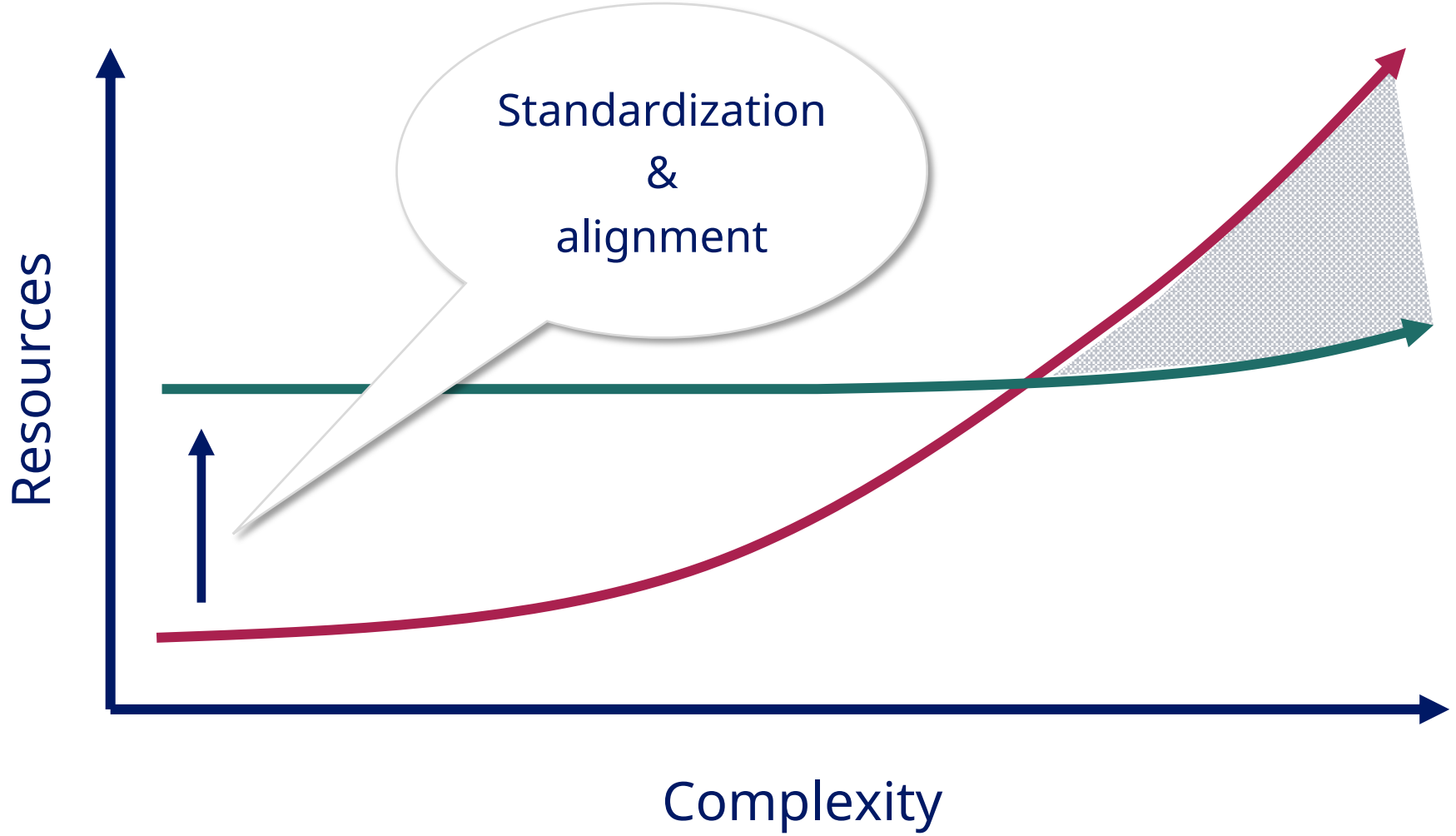

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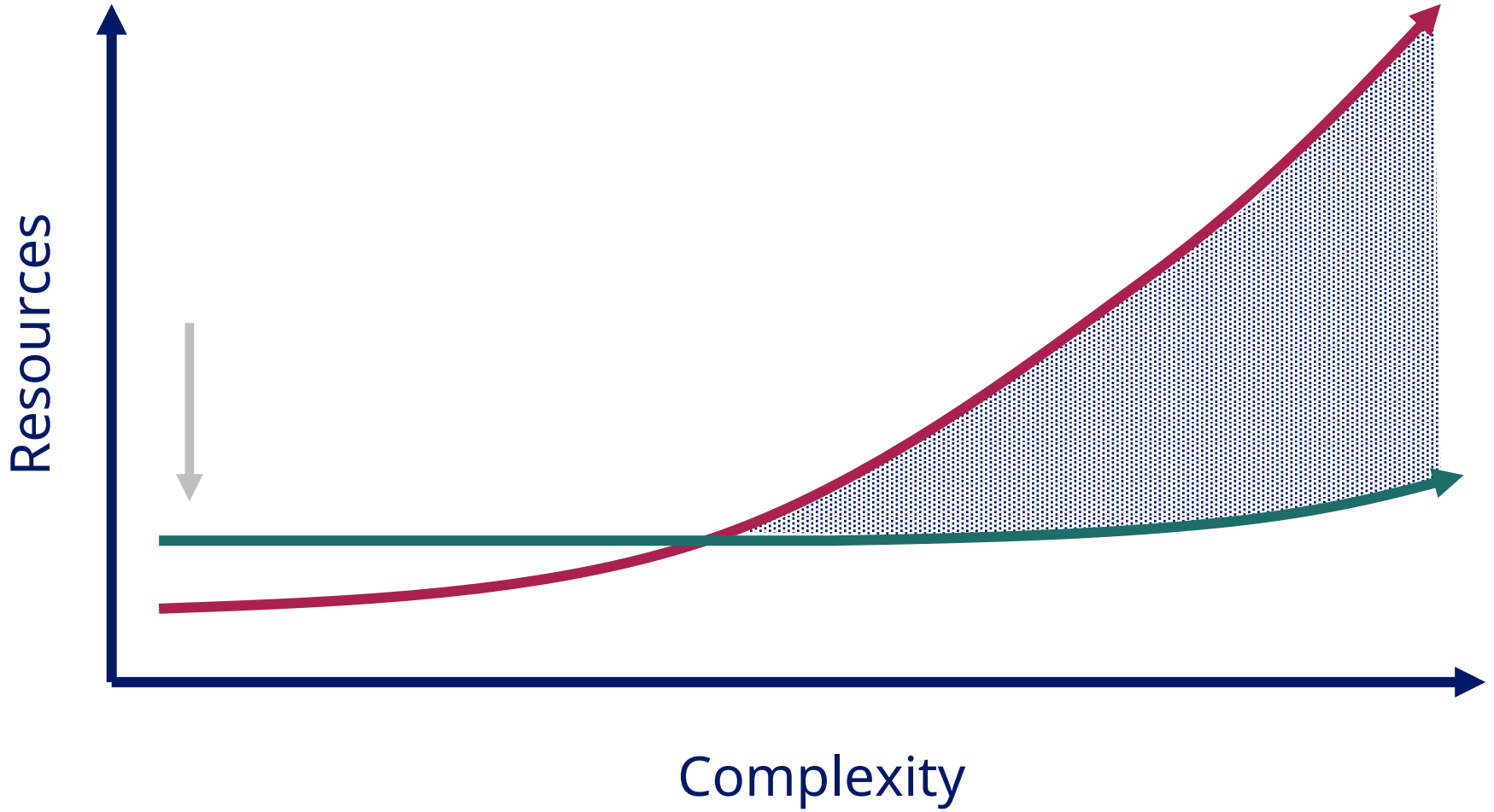

Moonshot

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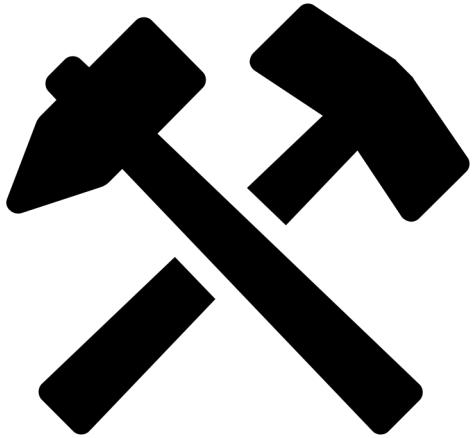
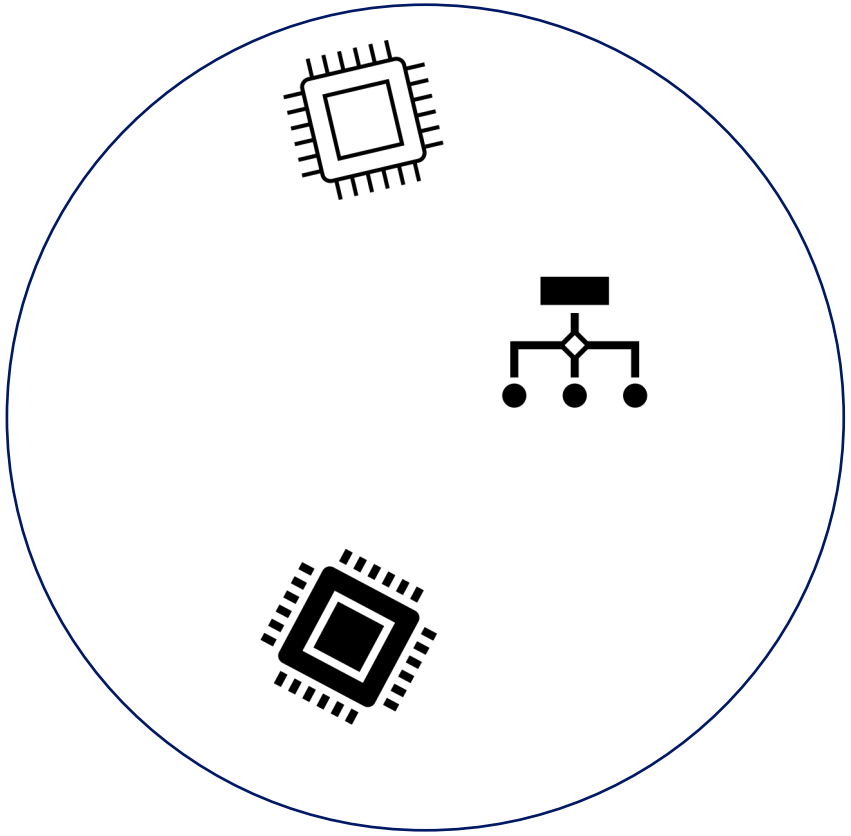
What is automation?

Tools vs.



Tools vs. Infrastructure/frameworks



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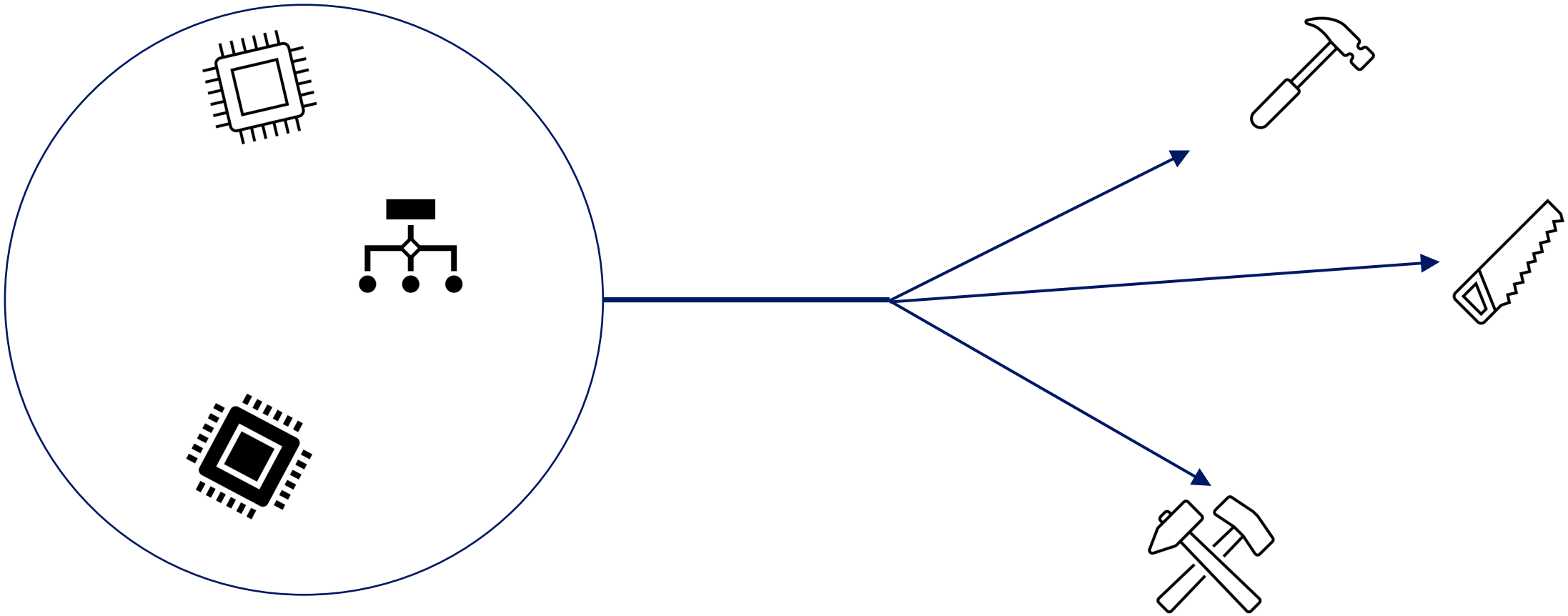

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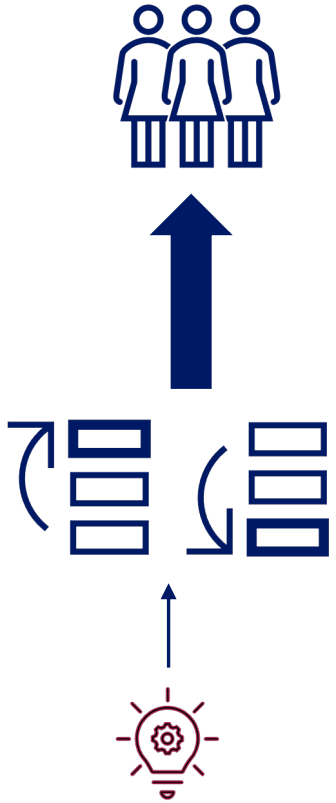

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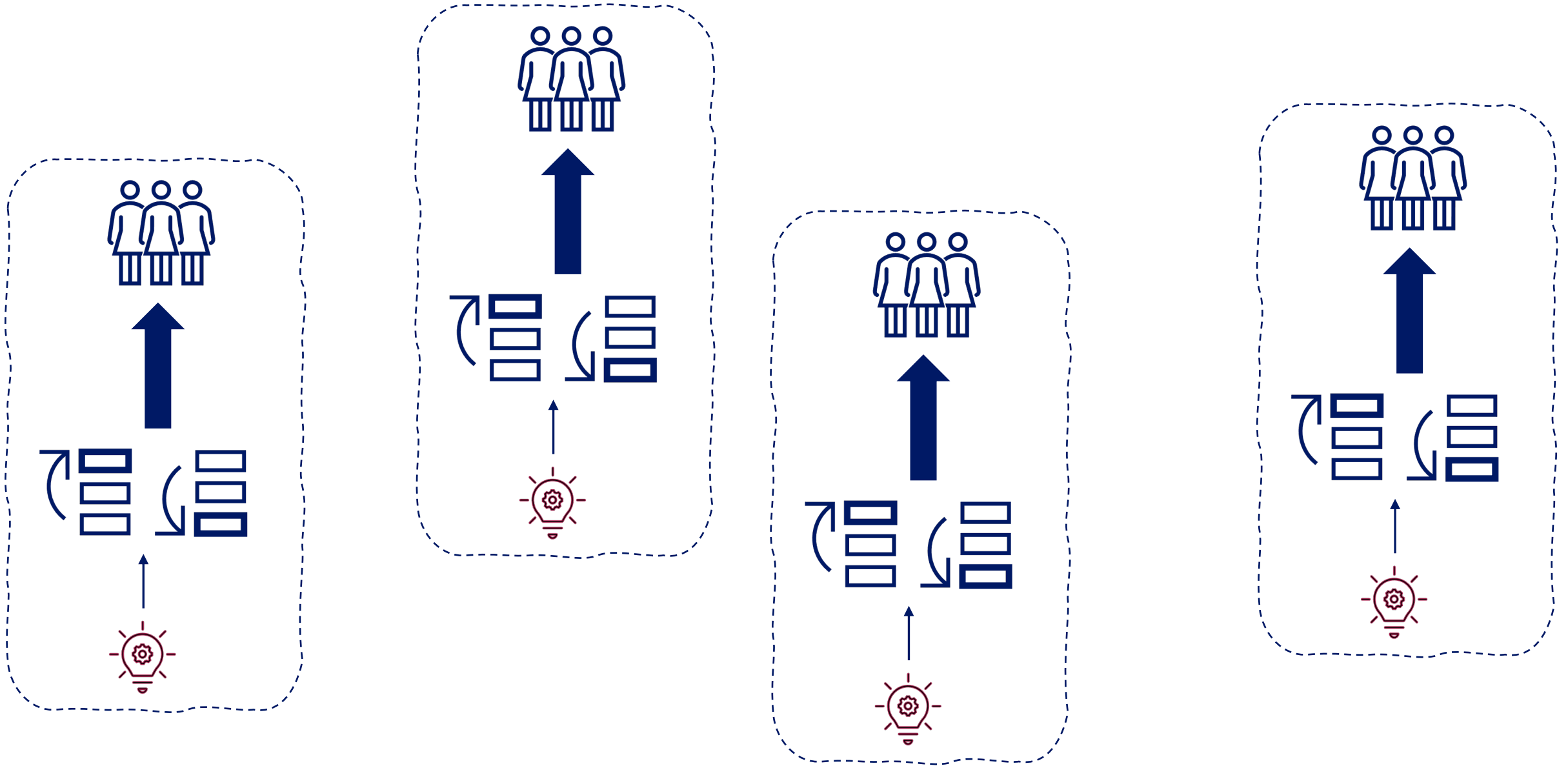

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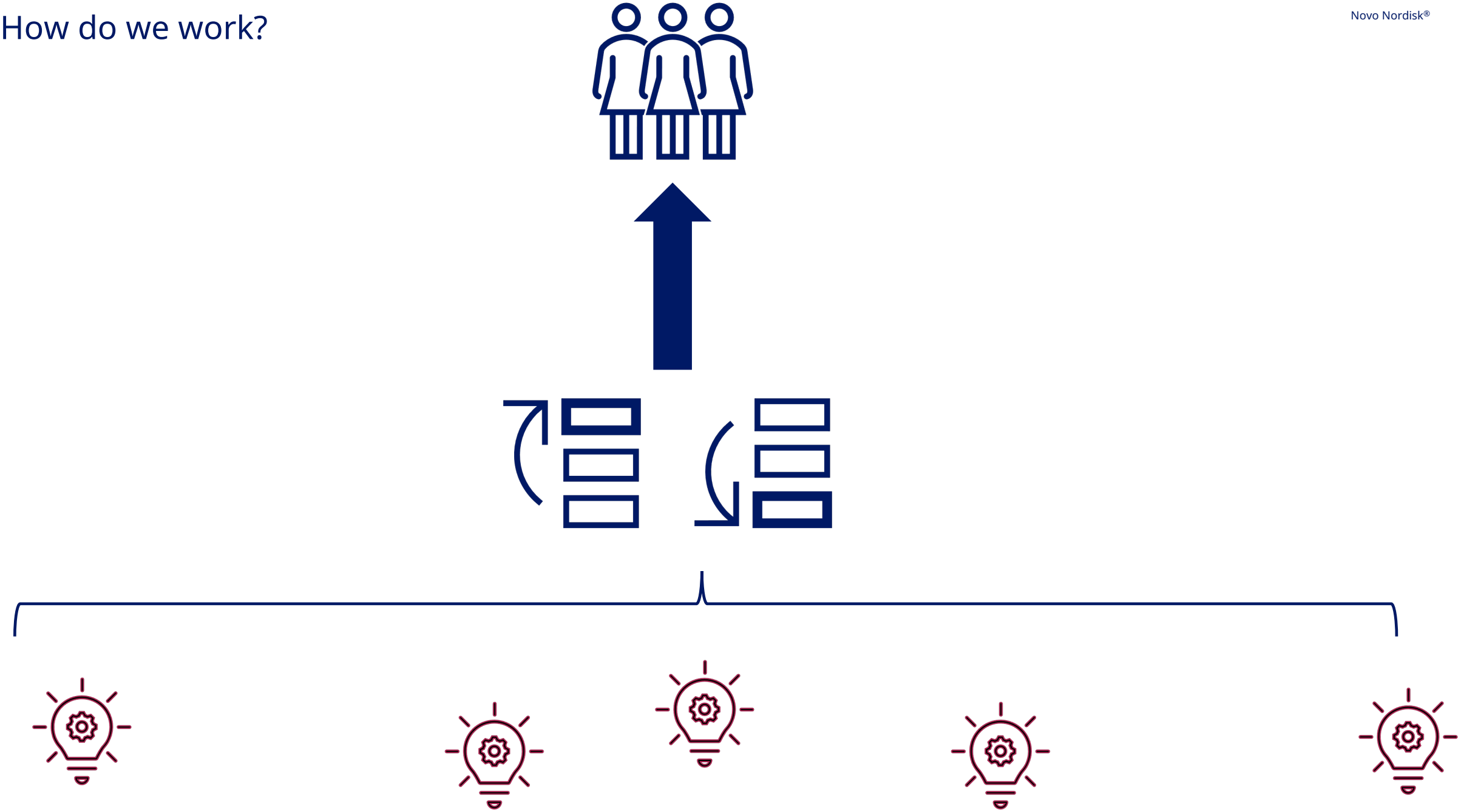

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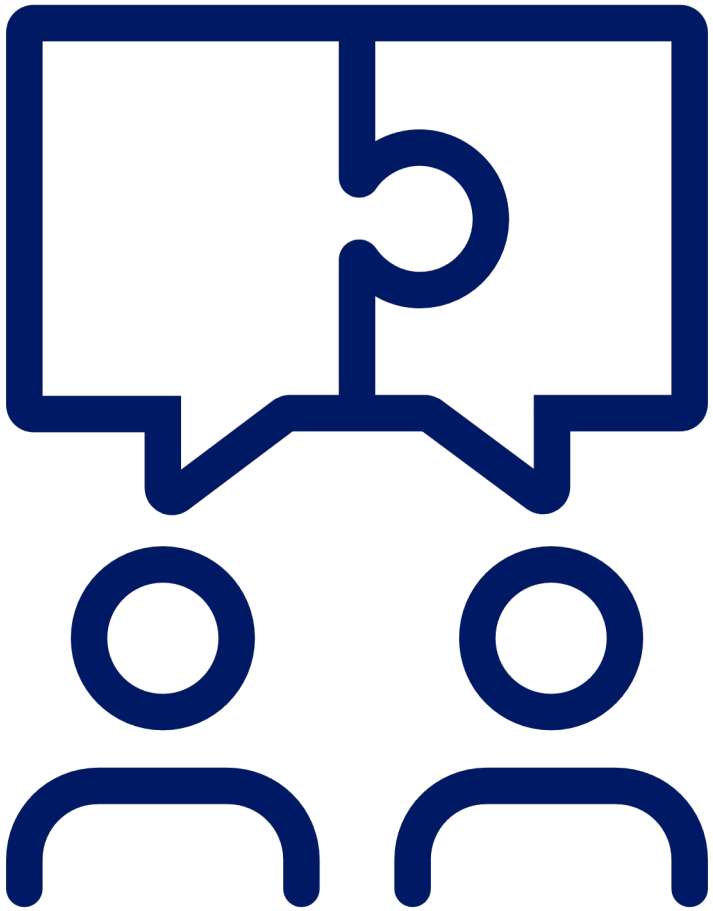

How do we work?

Trial experience

Interviewer: [redacted]
Role of interviewee in the trial: Trial programmer
[redacted]

FPFV – until DBL

Actions What happened? What did you do?	Joined 3-4 months into The trial – mock shells	mock-shells were already prepared ADaM programming of key data sets AEs, bleeding datasets physical Used the program master template and protocol as guidance	It was a tricky trial – data had to be transferred from two different trials - Was very problematic [redacted]	I had a lot of consultants involved (up to 8-9) – a lot of work to both handle my own programming and the issues from the consultants [Introducing Azure and git helps a lot – has worked differently on later trials – did not have to work over time]
Thoughts What did you think?	Nice way to understand the trial if inexperienced but not so relevant otherwise	What is needed and why is it needed – was new? Was new trial prog. Asked my lead programmer – this was very helpful	[redacted]	[redacted]
Feelings What did you feel?		Nice, I learned a lot. Now, we have the master ADaM templates + master model	Frustrated	Tough, tired, stressed that we would not make the timeline

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Interviewer: [illegible]
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Trial experience

FPFV – until DBL

Actions What happened? What did you do?	[Illegible]	I looked at outputs from SAD and MAD To pick the ones needed for EXP (not sure we made mock shells)	Find someone to do the programming – the main programmer did not have time to do the programming – got some help from consultants (Cognizant) who worked on the other trials and could use the programs	I programmed a lot of the programs as well [Illegible]	
Thoughts What did you think?	Nice	It was easy, just looked at MAD, and scale down what we did not need in EXP A lot of decisions had already been made – Protocol just said descriptive	I prefer working with people around me They were good, so that was nice, however, they were also many. So need to communicate the issues to all.	[Illegible] A lot of data had not been queried and that meant last minute changes and I had to update the programs last minute	
Feelings What did you feel?	I came in late in the trial	Nice, easy I liked the planning part	Cumbersome to keep track of all relevant information about issues across datasets is shared to all	[Illegible]	

Interviewer:
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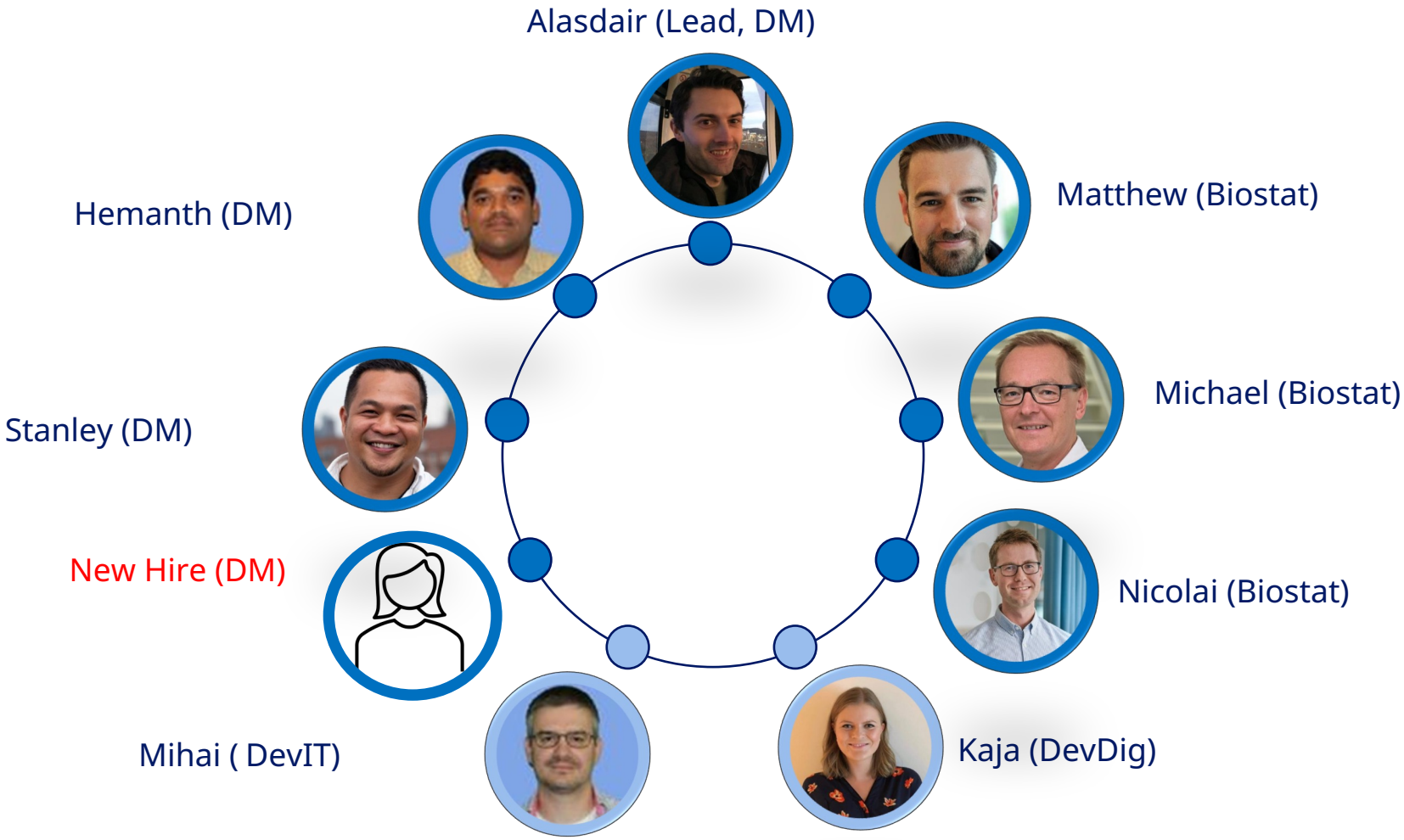
How do we work?

Data Science Automation Group



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What do we do?

Initial Priorities

	Data Management	Biostatistics
Proposed activities	**Kassandra** (automated test data pipeline: EDC to TFL)	
	Automated query management solution	**AMNOG** dossier automation
	Automated comparison of SDTM datasets between DBLs	Automation of safety narratives
	Increased automation in coding of ConMeds	Framework for standard programming

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