

# Automation in Biostatistics at Novo Nordisk

## LI05

**Matthew Phelps**

**Statistical Programming Specialist, Novo Nordisk A/S**

**November 2022**



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

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

# Agenda

# **1. Why automation?**

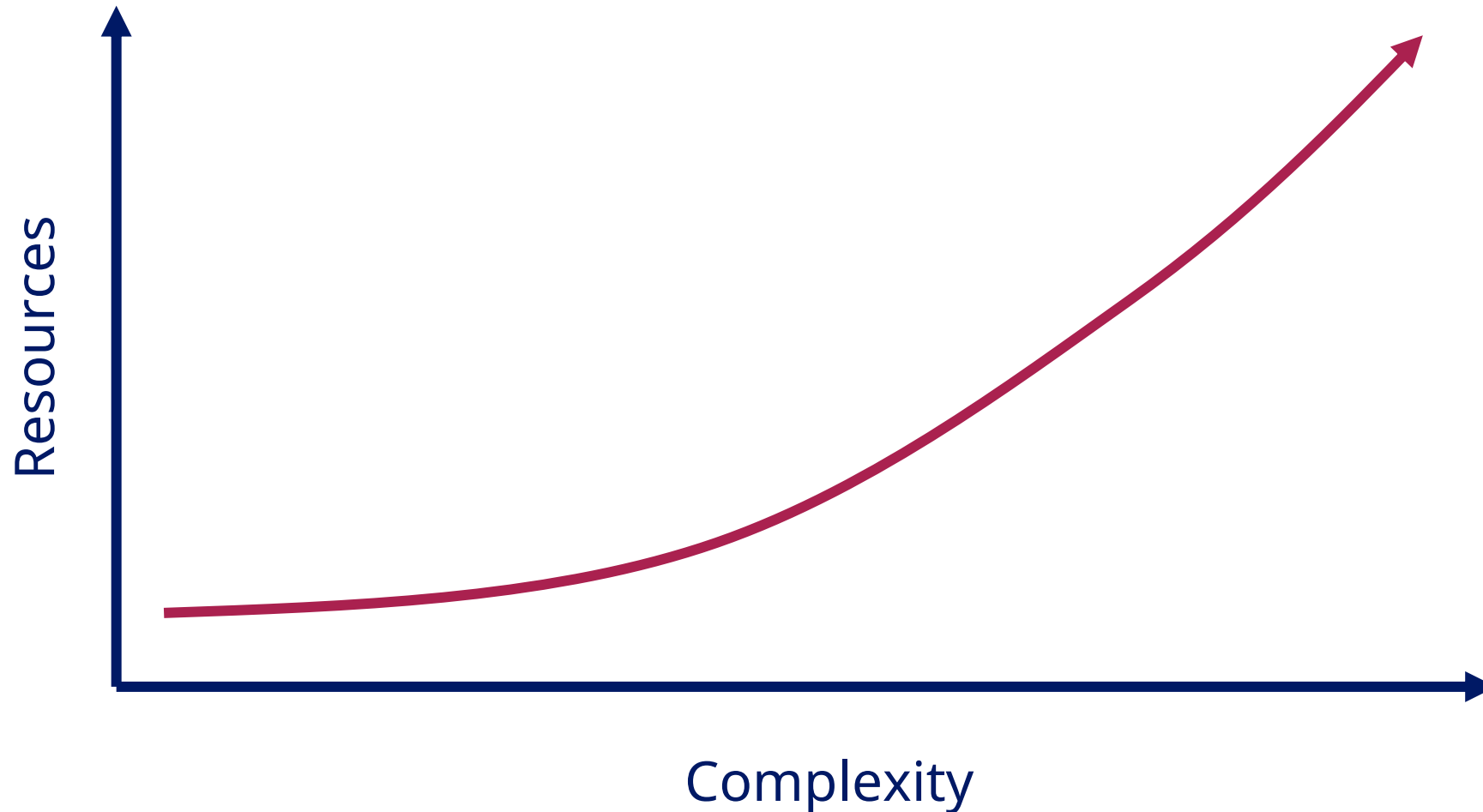
2. What is automation?

3. How do we work?

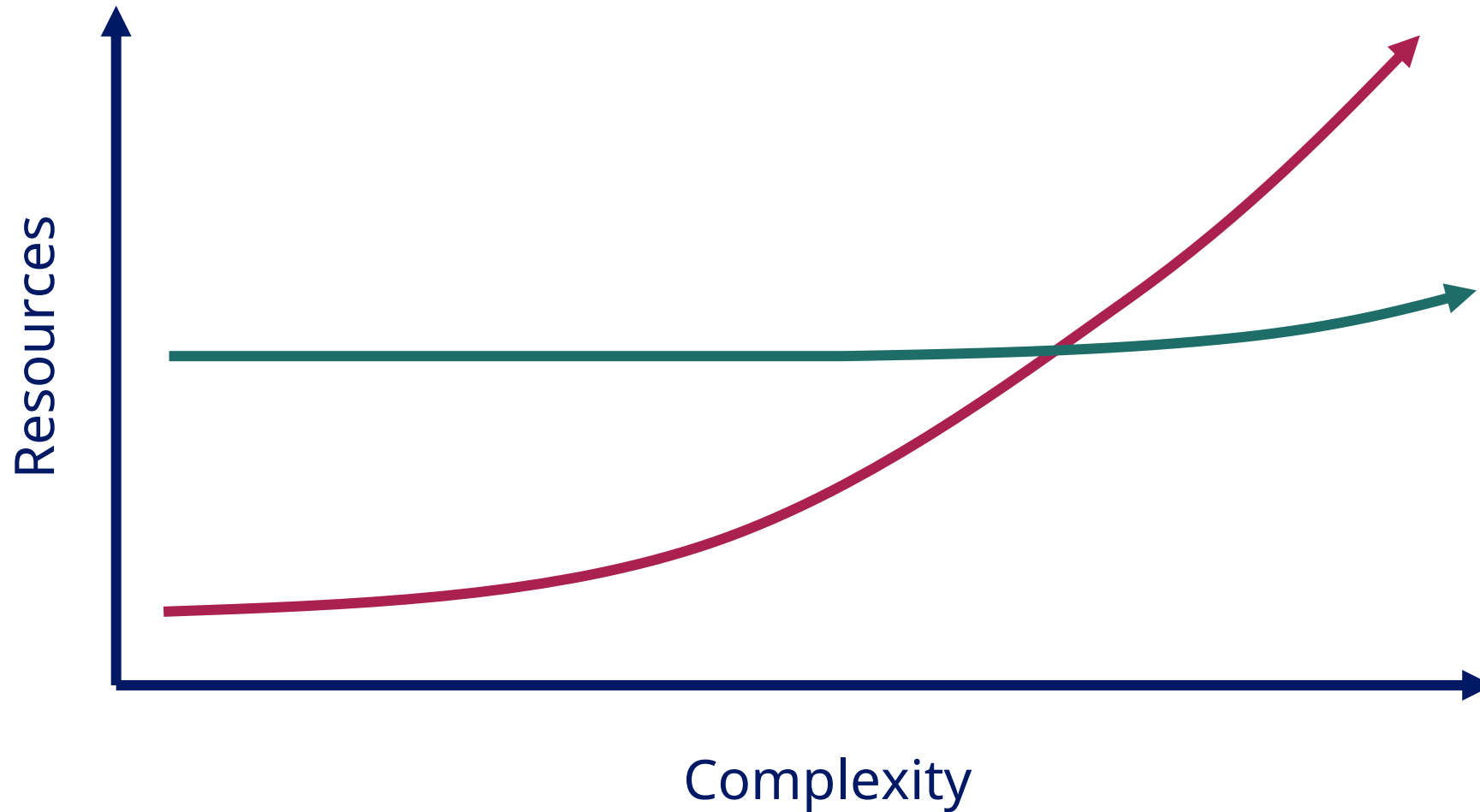
4. What do we do?

Agenda

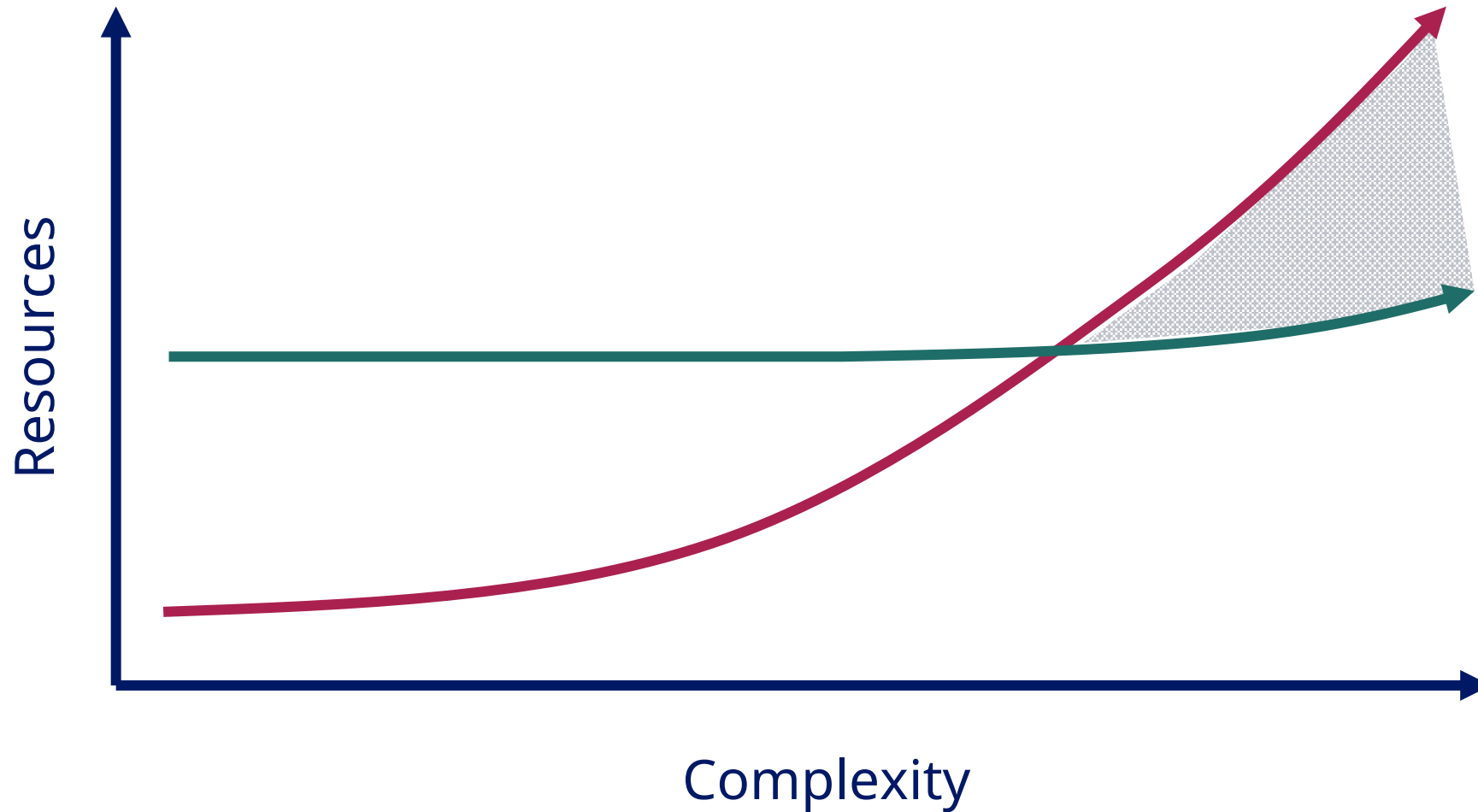
# Increasing complexity



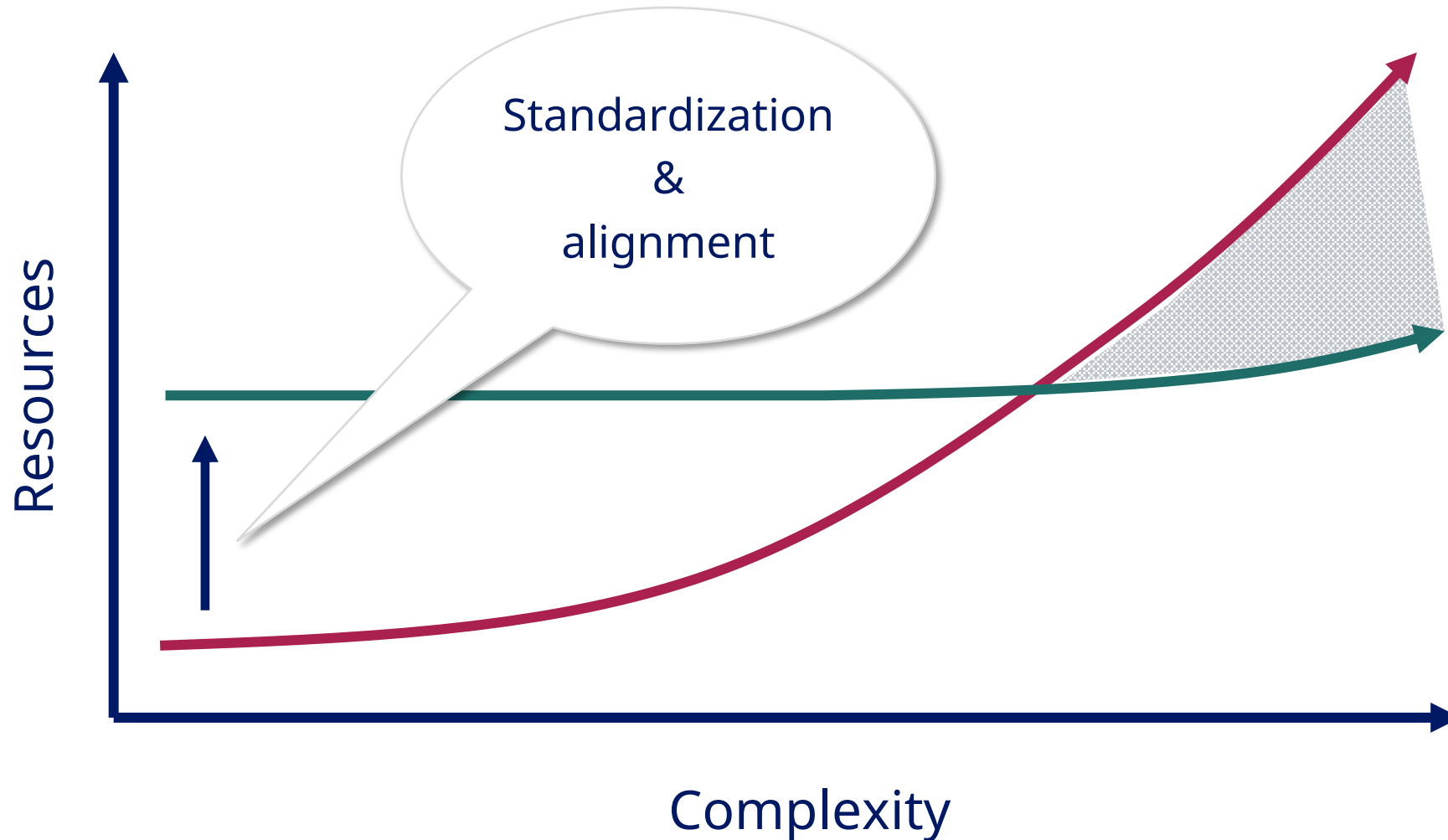
# Increasing complexity



# Increasing complexity

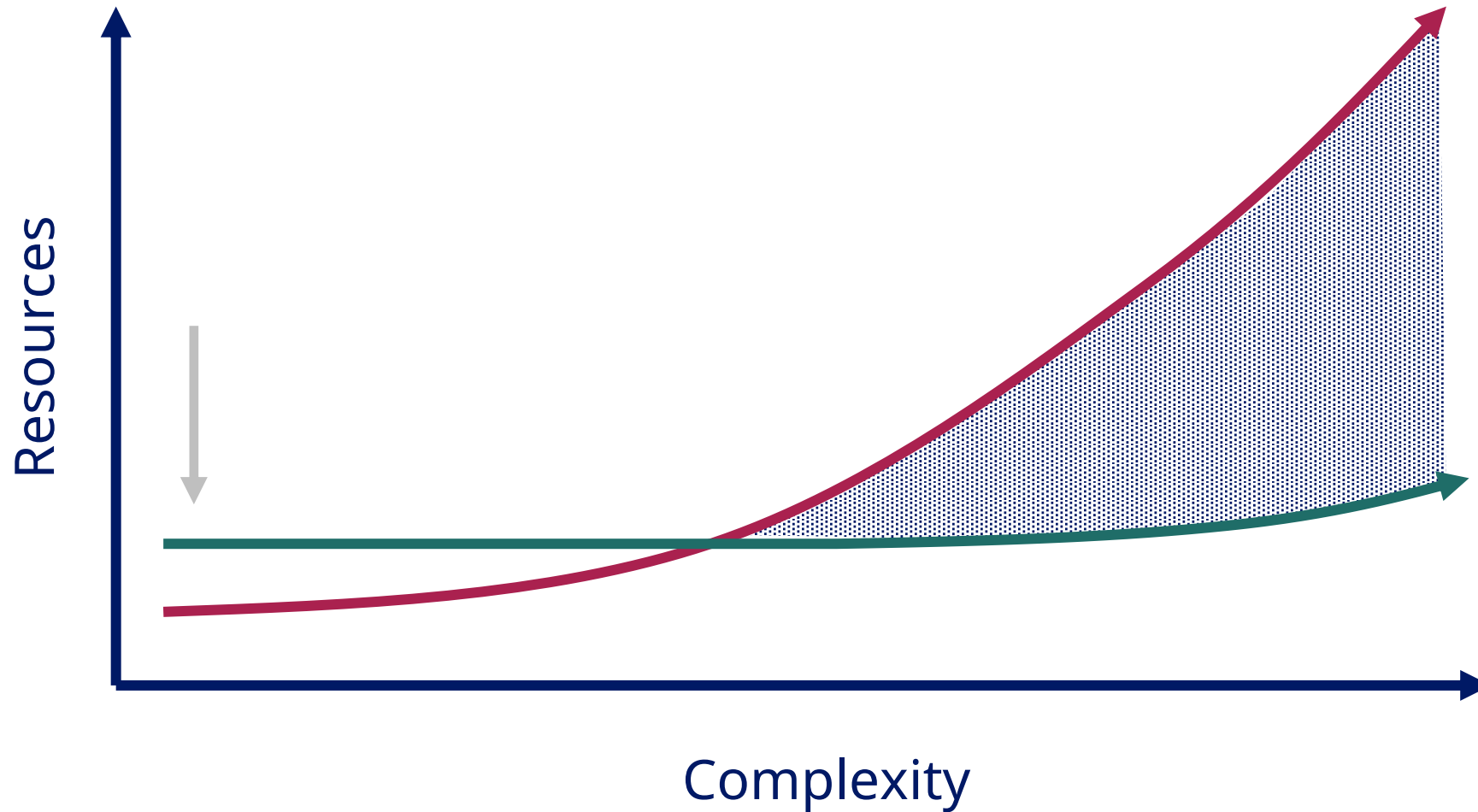


# Increasing complexity





# Increasing complexity



# Moonshot

- Submit **4 days after Last Patient Last Visit**



# Moonshot

- Submit **4 days after Last Patient Last Visit**
- to the **4 most important markets** (USA, China, EU and Japan) - and...



# Moonshot

- Submit **4 days after Last Patient Last Visit**
- to the **4 most important markets** (USA, China, EU and Japan) - and...
- secure successful access and launch **4 days after approval**



# Moonshot

- Submit **4 days after Last Patient Last Visit**
- to the **4 most important markets** (USA, China, EU and Japan) - and...
- secure successful access and launch **4 days after approval**



1. Why automation?

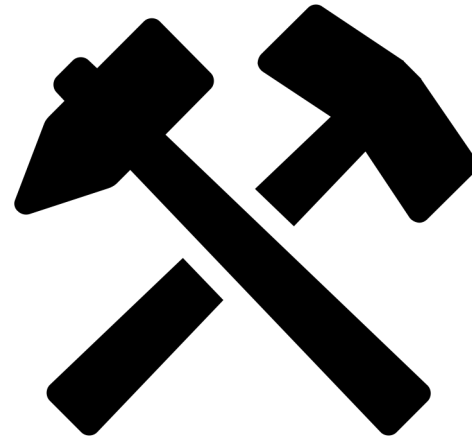
**2. What is automation?**

3. How do we work?

4. What do we do?

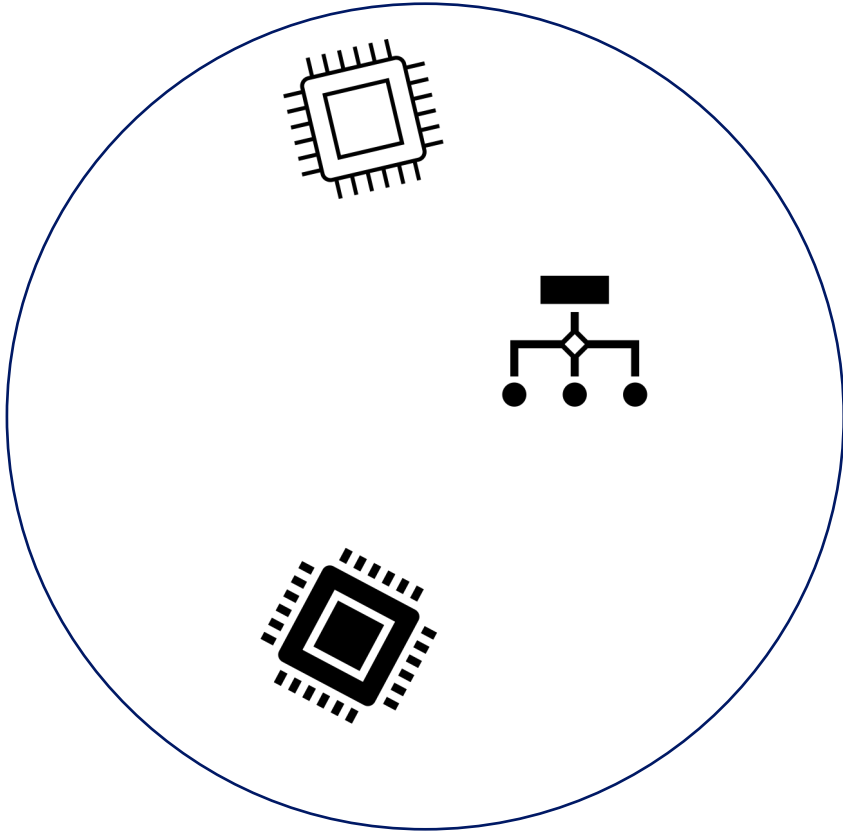
Agenda

# Tools vs.



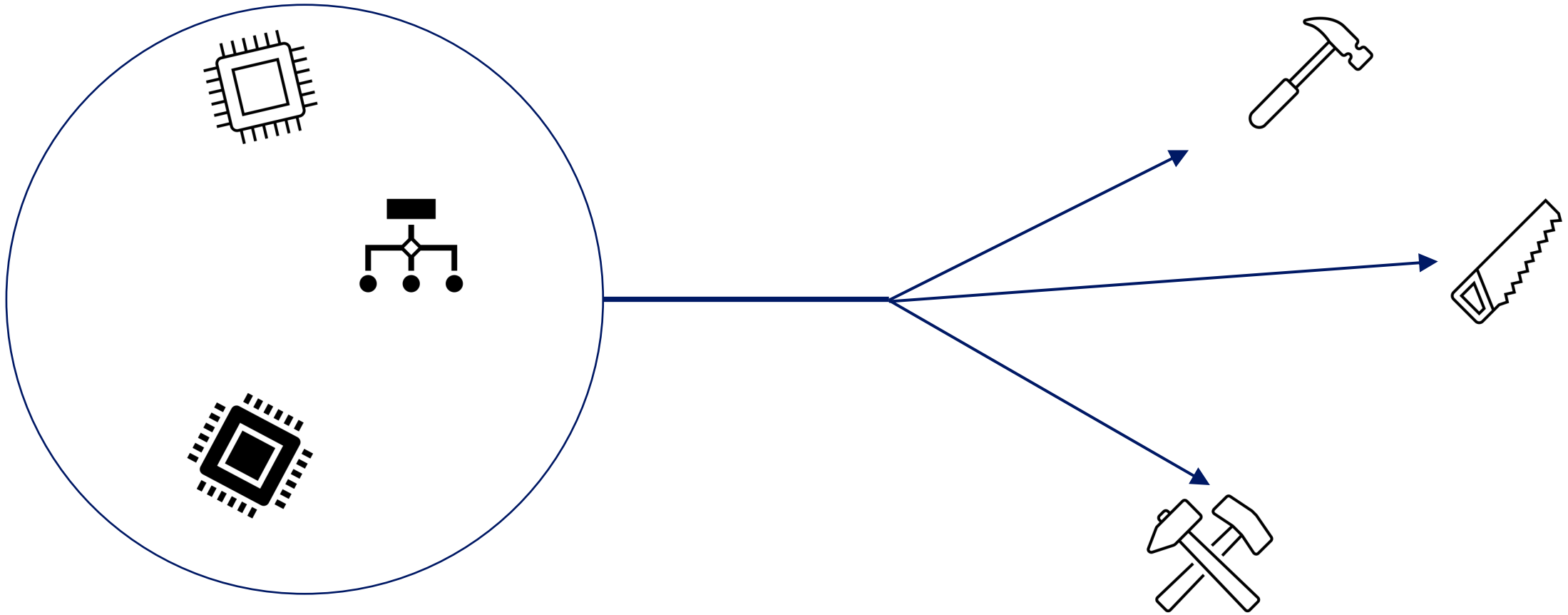
What is automation?

# Tools vs. Infrastructure/frameworks





# Tools vs. Infrastructure/frameworks



1. Why automation?

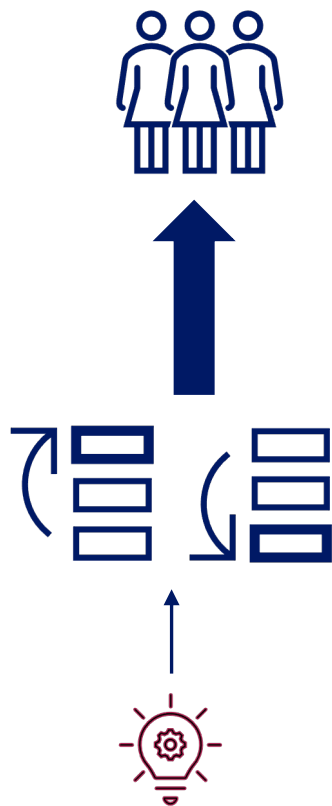
2. What is automation?

**3. How do we work?**

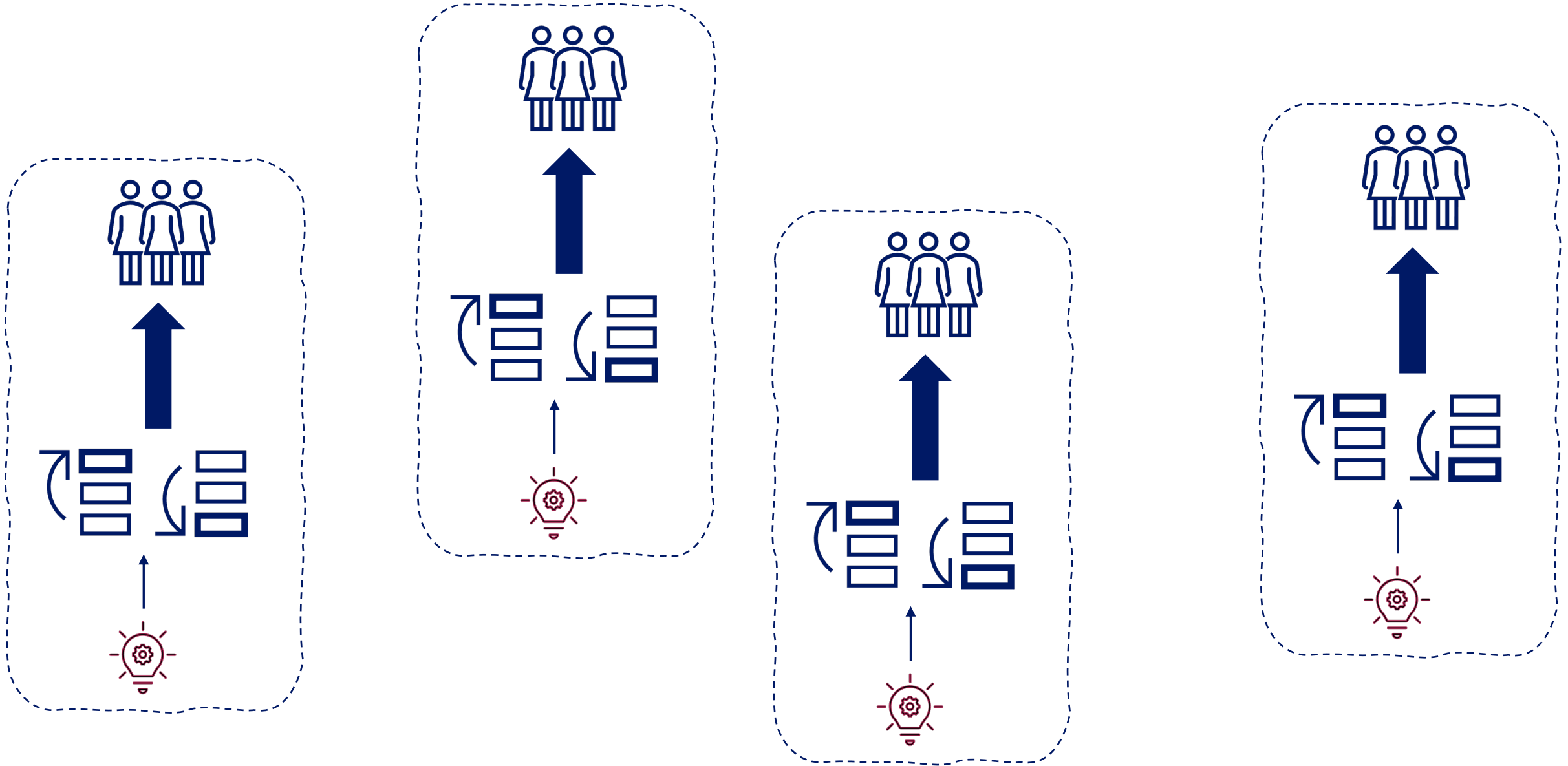
4. What do we do?

# Agenda

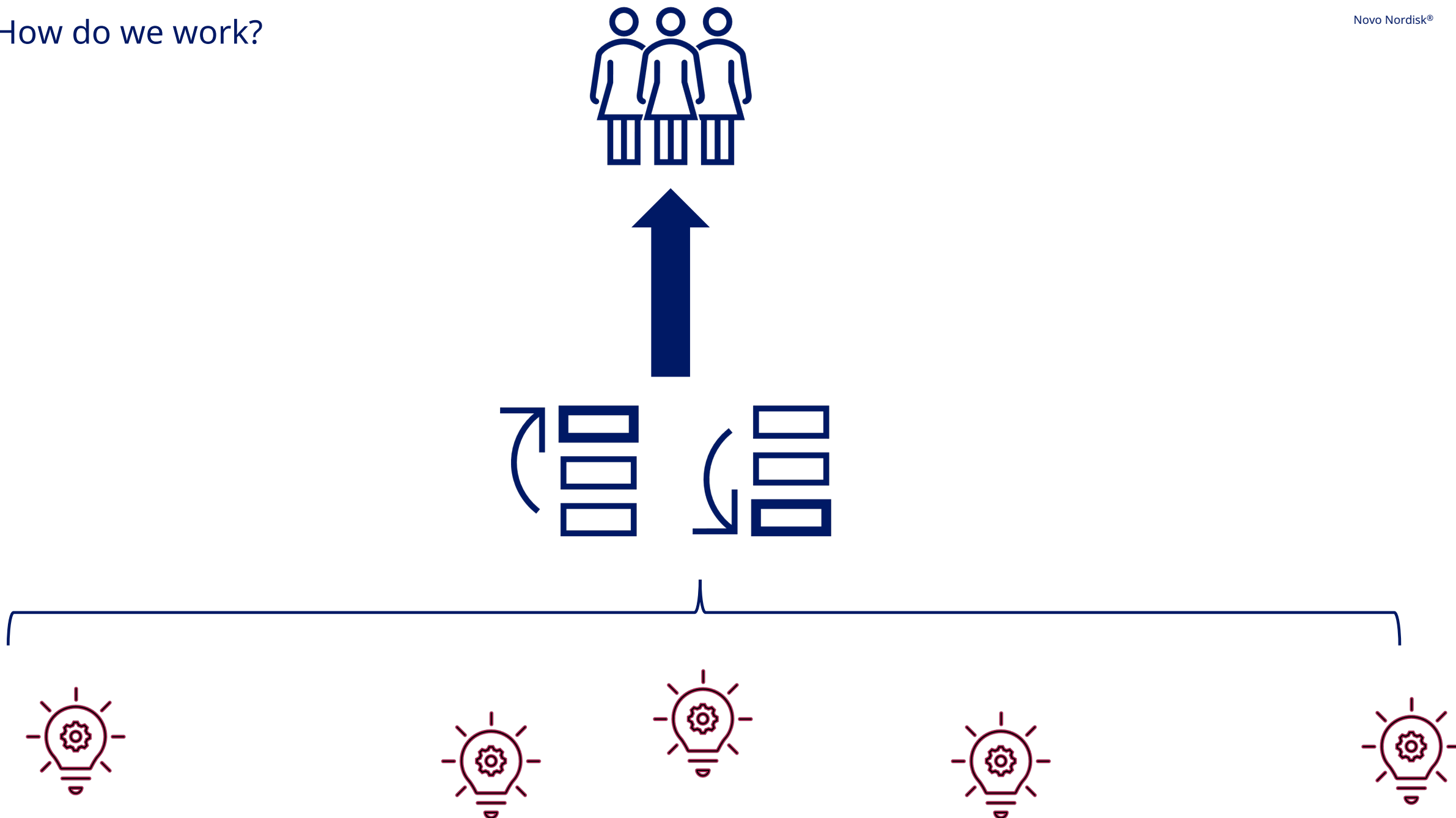
# How do we work?



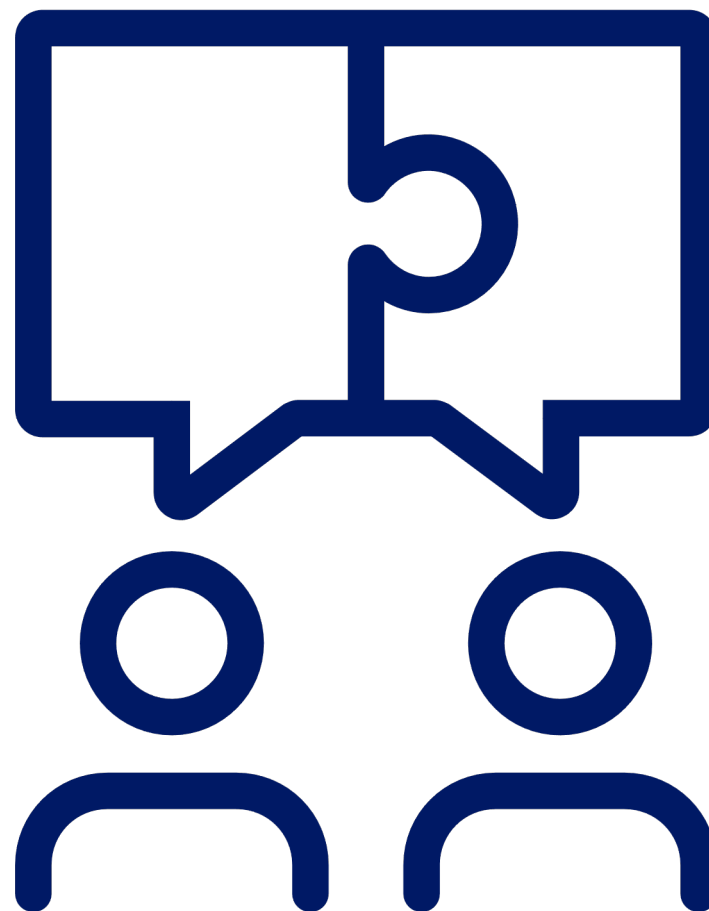
# How do we work?



# How do we work?



## How do we work?



# How do we work?

## Trial experience

FPFV – until DBL

Interviewer: **Interviewer**  
 Role of interviewee in the trial: **Trial programmer**  
**Trial ID: 1111**

<b>Actions</b> 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  <i>Specified a lot of variables          Supporting DBL - the ADaM programmer          a lot          A lot of data checking</i>	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]
<b>Thoughts</b> 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	<i>Why do I have to do all this data checking?          I have my own code, that's checked and          we are the ones looking into the data          checking          Not sure ADaM team to be helped - I just          deadlines on them - when I needed the          data</i>	<i>This is time consuming and boring - but          not that we progress towards the          deadline. Maybe it is just me being new.           Could not work within normal working          hours for the last approx. 2 months before          DBL start and trial prog.</i>
<b>Feelings</b> 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

How do we work?

Trial experience

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	It v tra - W
---	---	--	--------------------

Trial experience

FPFV – until DBL

Thoughts What did you	Actions What happened? What did you do?	The same In DM al In betw	I looked at outputs from SAD and	Fi
--------------------------	---	---------------------------------	----------------------------------	----

Feelings What did you	Thoughts What did you think?	Nice
--------------------------	---------------------------------	------

Trial experience

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	It was a tricky trial – data had to be transferred from two different trials - Was very problematic <i>Spent a lot of time Supporting the other trial programmer and A lot of data checking</i>	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	<i>Why do I have to do all this data checking? I have my own code. Had to check what we are the ones loading into the data checking Not sure if I had to be helped - I put deadlines on them - when I needed the data</i>	<i>This is time consuming and boring - but now that we progress towards the deadline. Maybe it is just me being new.  Could not work within normal working hours for the last approx. 2 months before DBL. Great test and trial prog.</i>
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

Trial experience

FPFV – until DBL

Actions What happened? What did you do?	The same people worked on all parts In DM and TM – EXP part ended in In between of interims on SAD and MAD	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  <i>I was basically doing the data checking</i>
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.	<i>Interim DBLs on SAD and MAD taking the same people from TM and DM so they had no time until 2 weeks before DBL.</i>  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	<i>Something - I had planned integration meetings shortly after DBL, but had to move them because DBL was delayed. Managed to have an integration meeting right after DBL, then there were updates to the DBL data that we had to take into, so DBL not work as well.</i>  <i>This is very frustrating, we are very dependent on each other. DBL will never happen. Not alone in trying to make the deadline.</i>

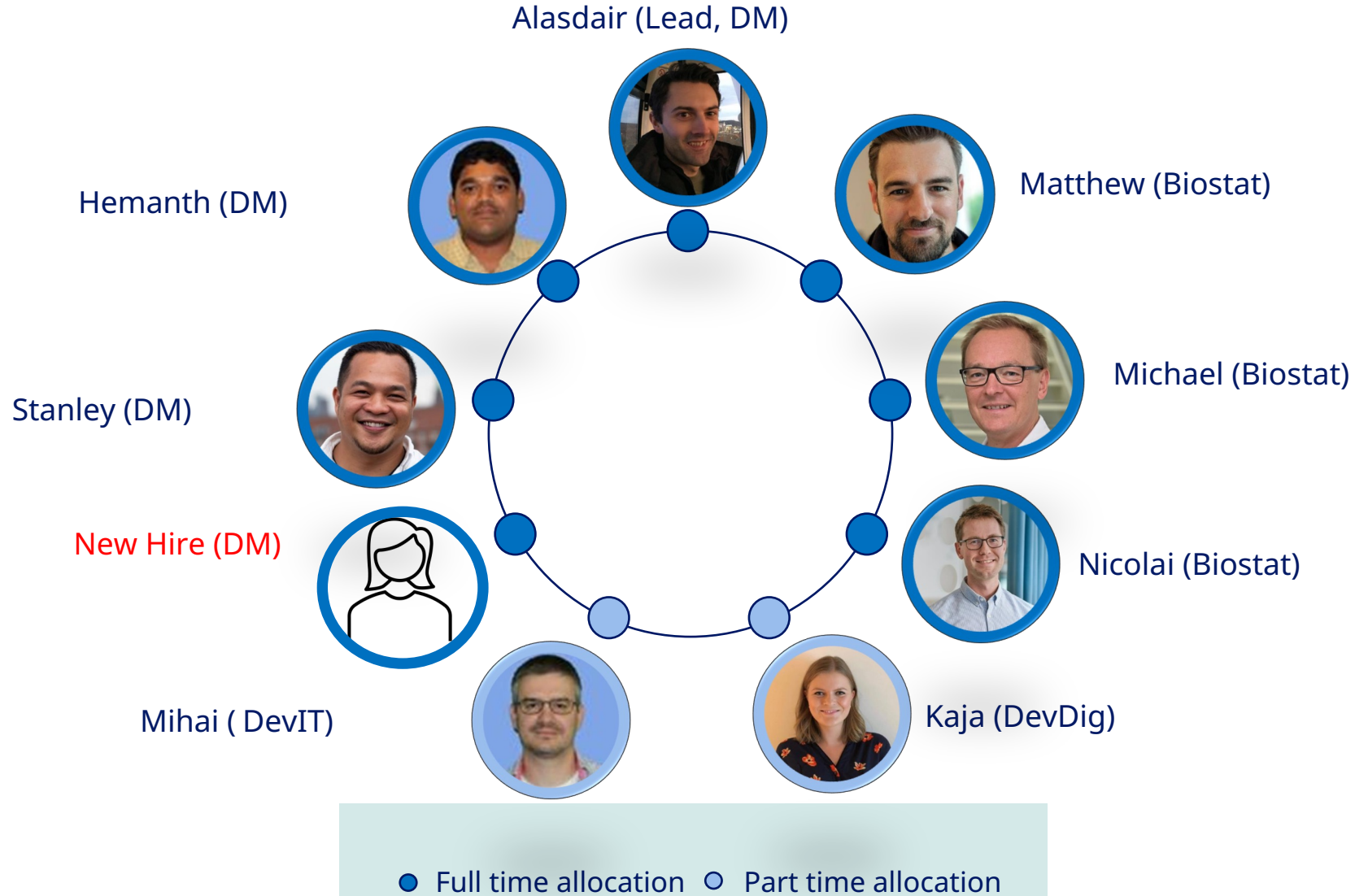
Interviewer: *What was the  
Role of interviewee in the trial: Trial  
programmer  
Trial ID: 104610*

red ta sets	It was a tricky trial – data had to be transferred from two different trials - Was very problematic  <i>Spent a lot of time Supporting the other trial programmer and A lot of data checking</i>	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]
ate and	<i>Why do I have to do all this data checking? I have my own code. Had to check what we are the ones loading into the data checking Not sure if I had to be helped - I put deadlines on them - when I needed the data</i>	<i>This is time consuming and boring - but now that we progress towards the deadline. Maybe it is just me being new.  Could not work within normal working hours for the last approx. 2 months before DBL. Great test and trial prog.</i>
eeded – was d my lead pful	Frustrated	Tough, tired, stressed that we would not make the timeline



How do we work?

# Data Science Automation Group



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

**4. What do we do?**

# Agenda

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

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

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

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

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

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



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

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

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

[mewp@novonordisk.com](mailto:mewp@novonordisk.com)

Matthew Phelps

