

Trials Are Out Pools Are In

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Statistical Programming Specialist

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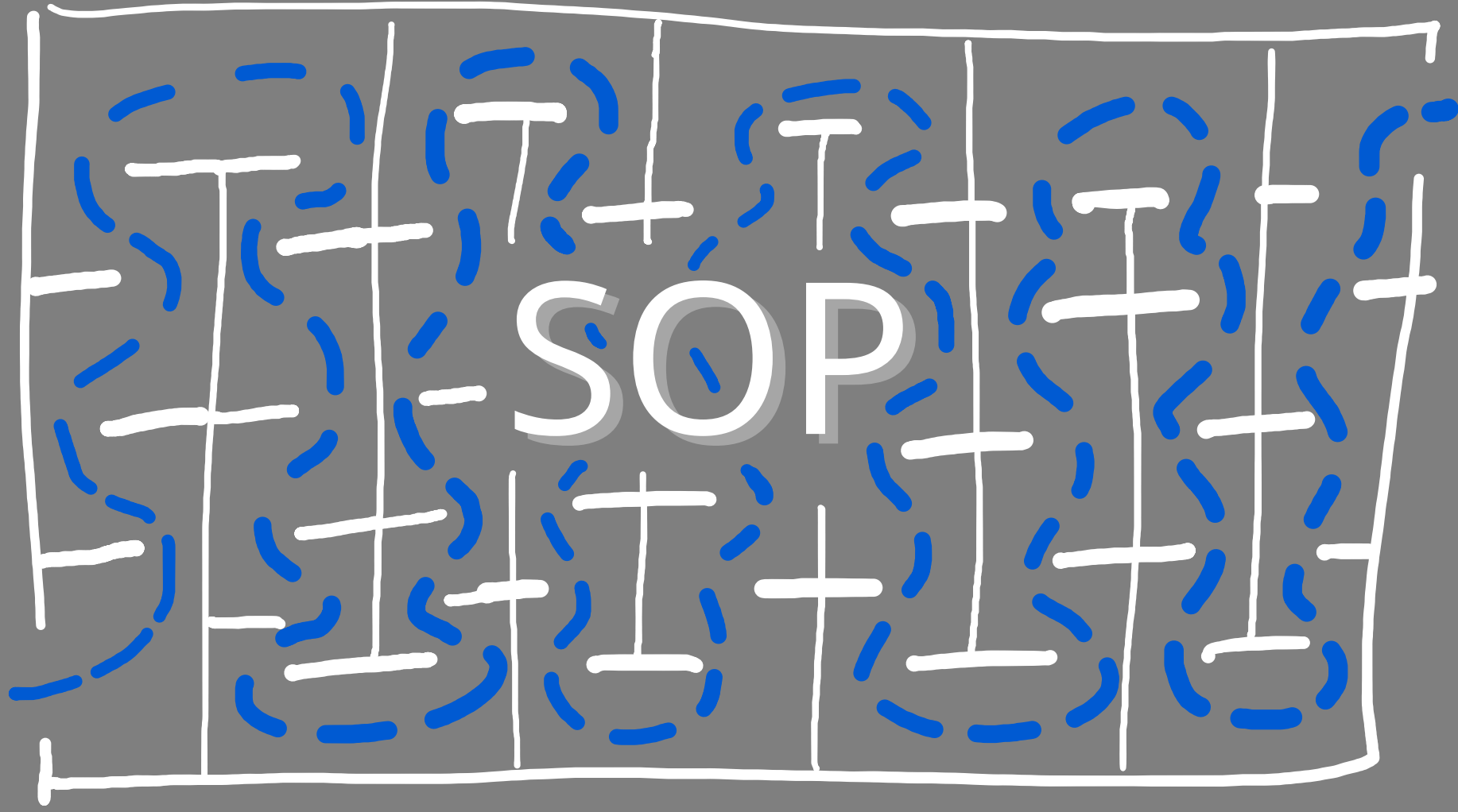
PHUSE US CONNECT 2023 – ET08

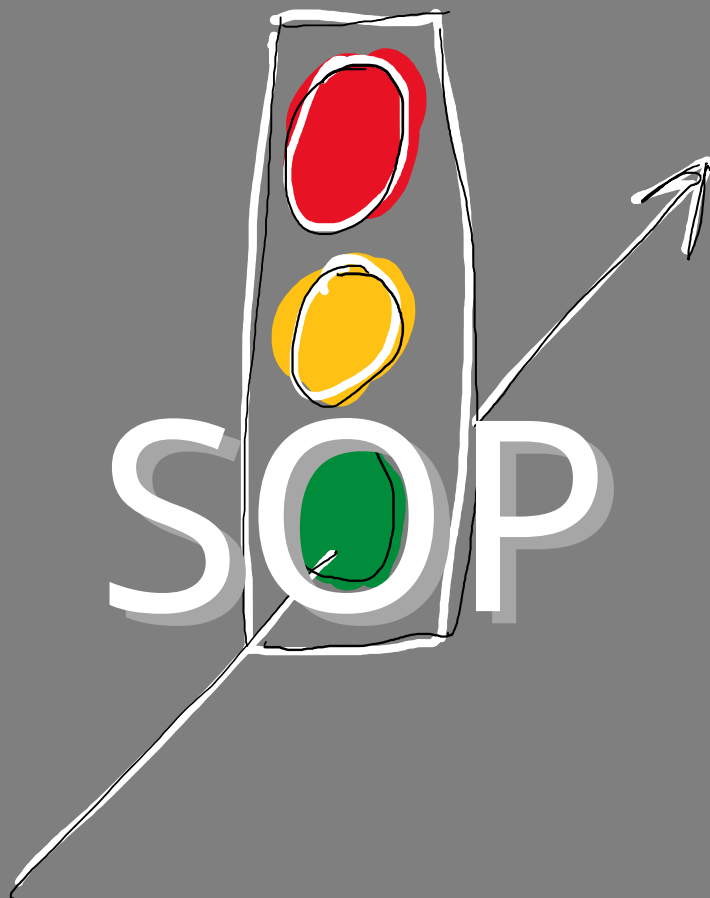
Views and opinions expressed are those of the speaker and not necessarily Novo Nordisk





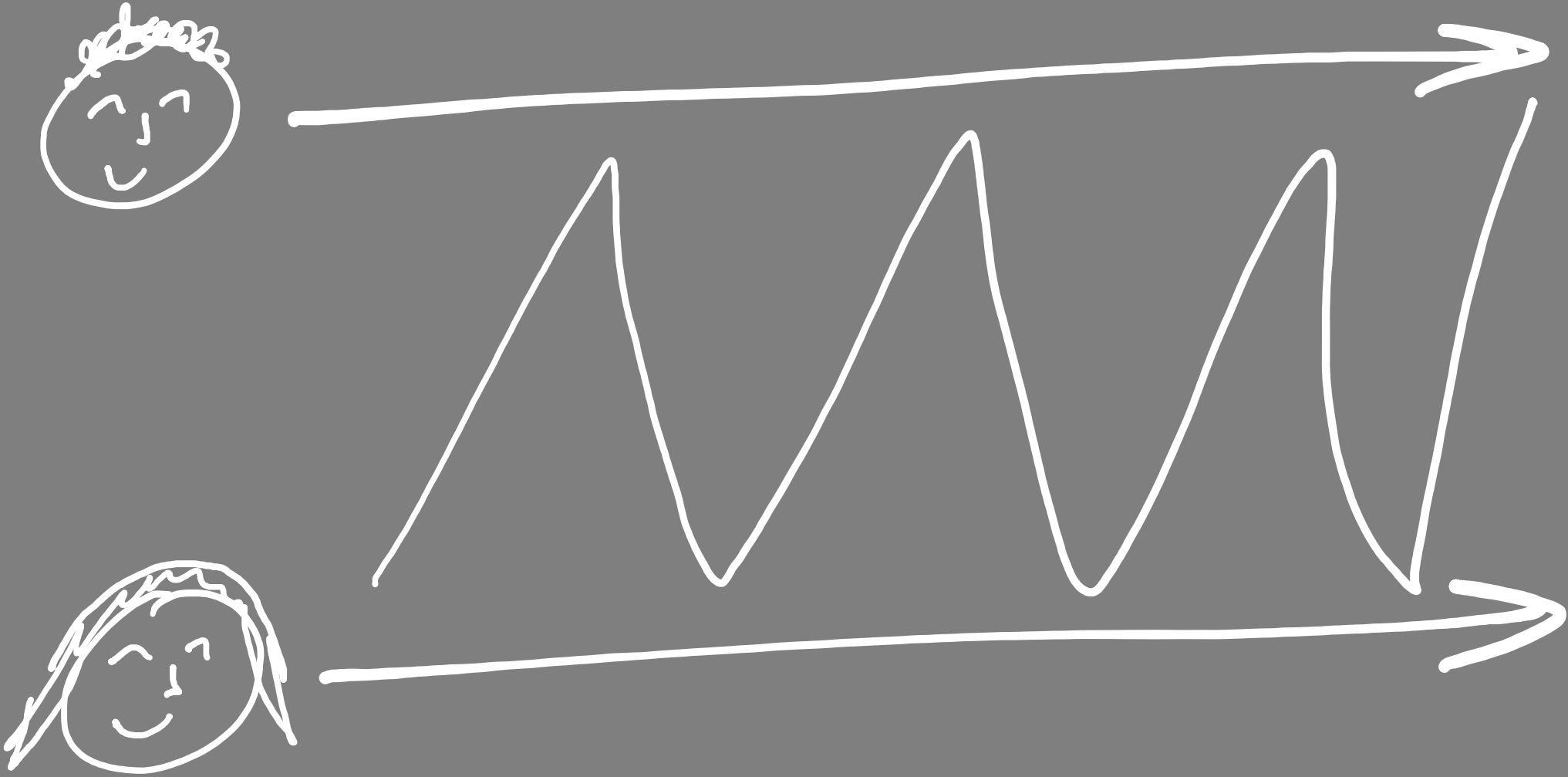
SOP



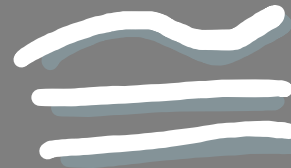




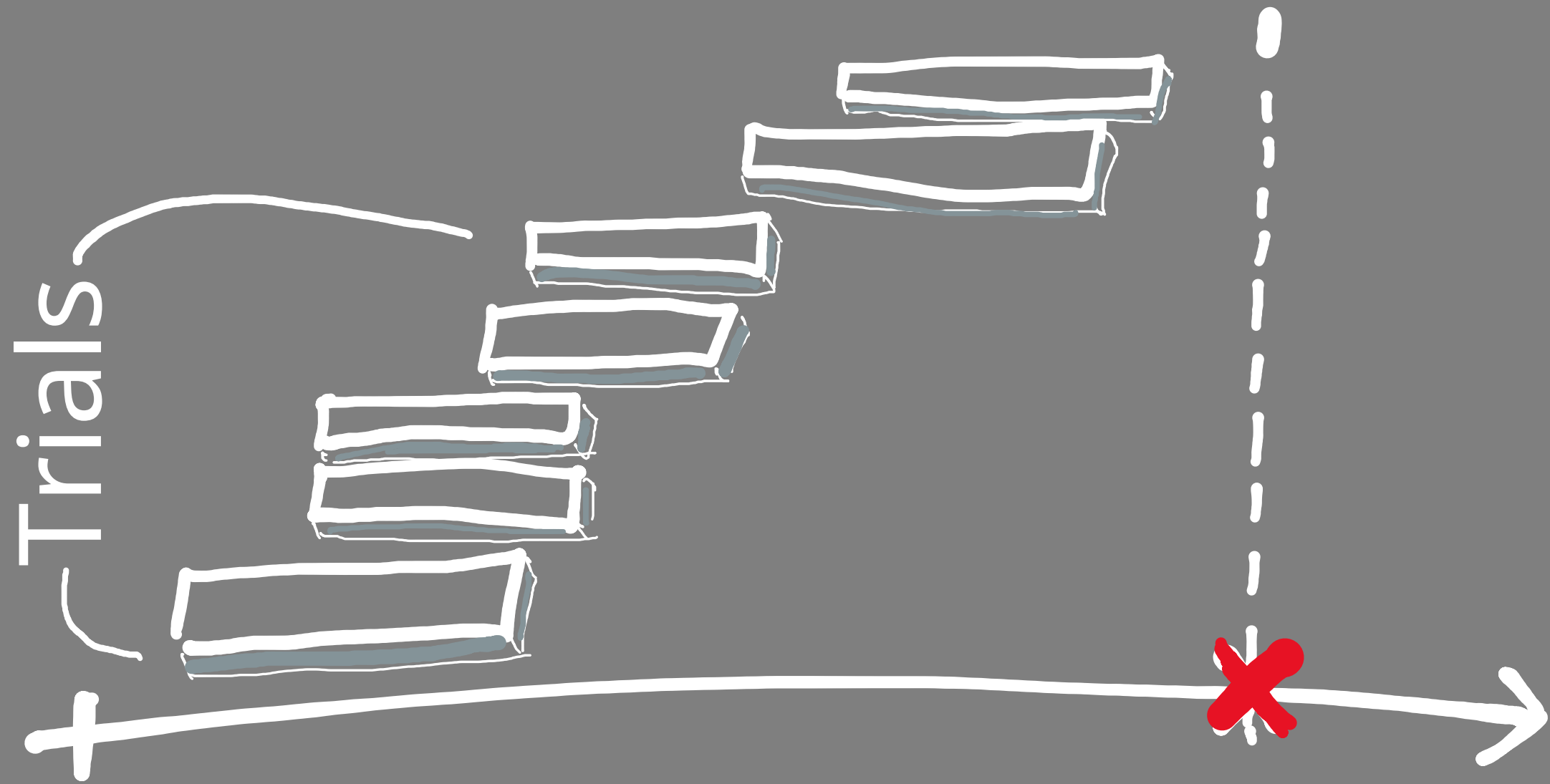
The alignment problem

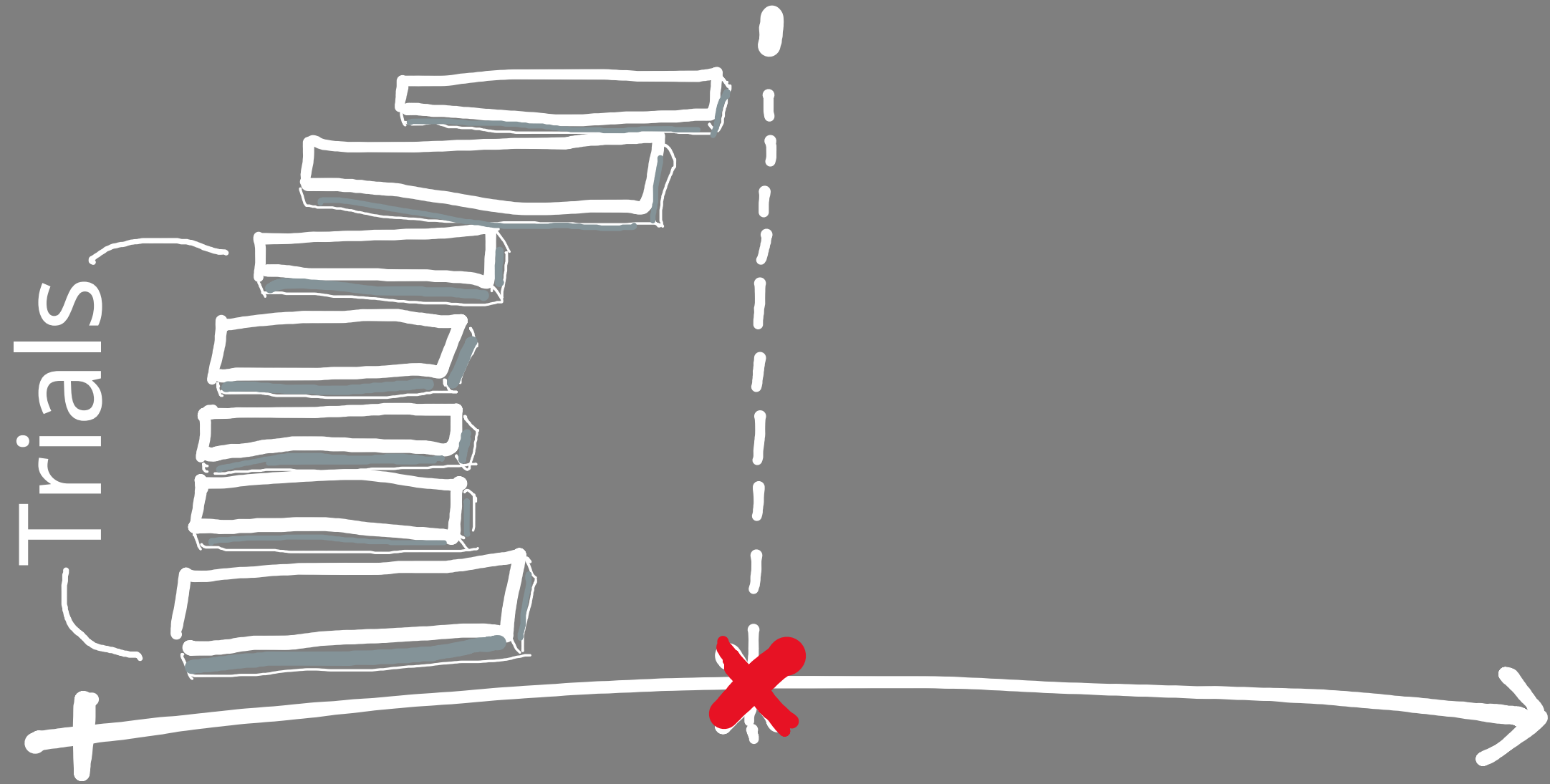


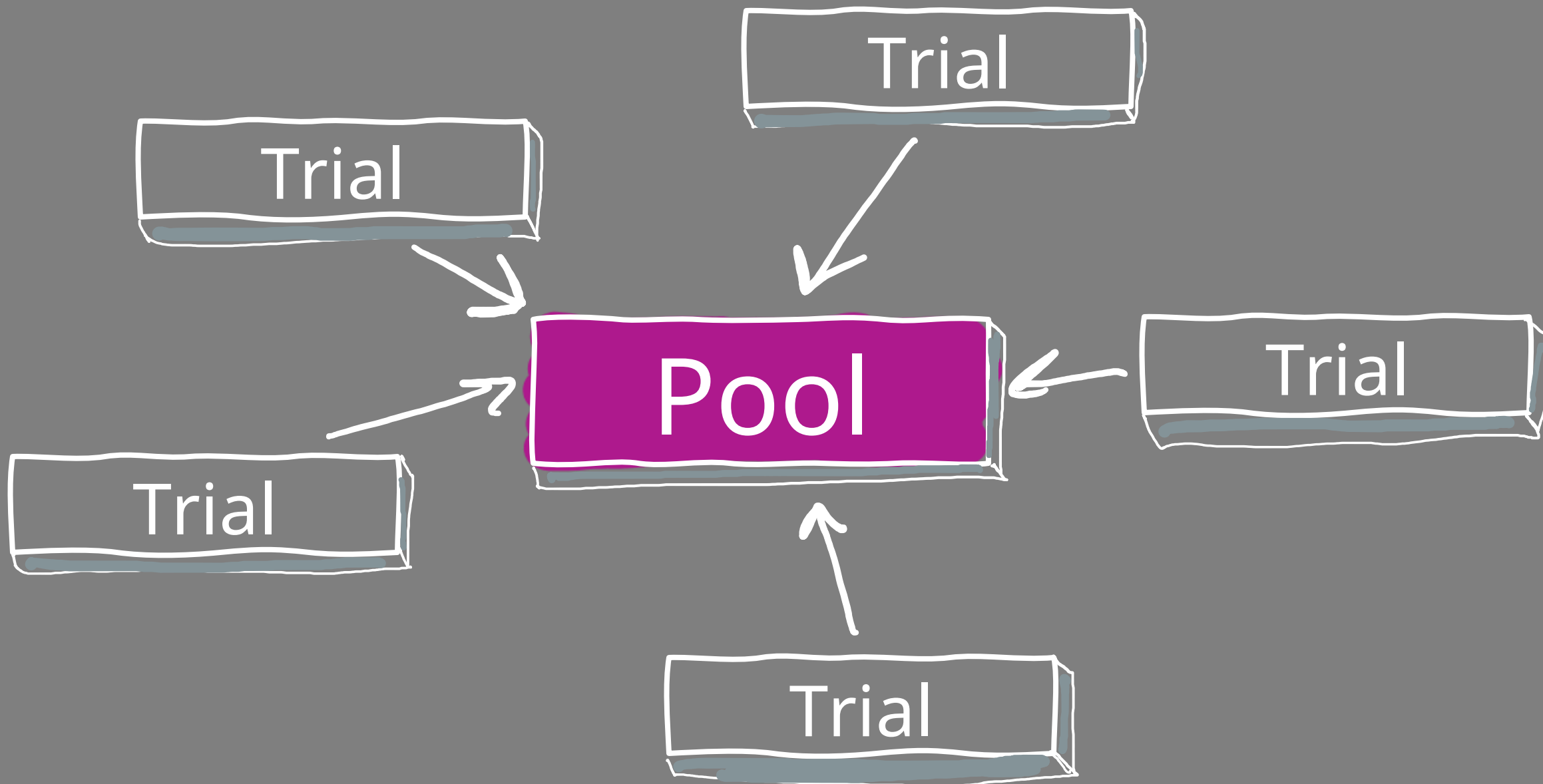
Alignment of
deliverables

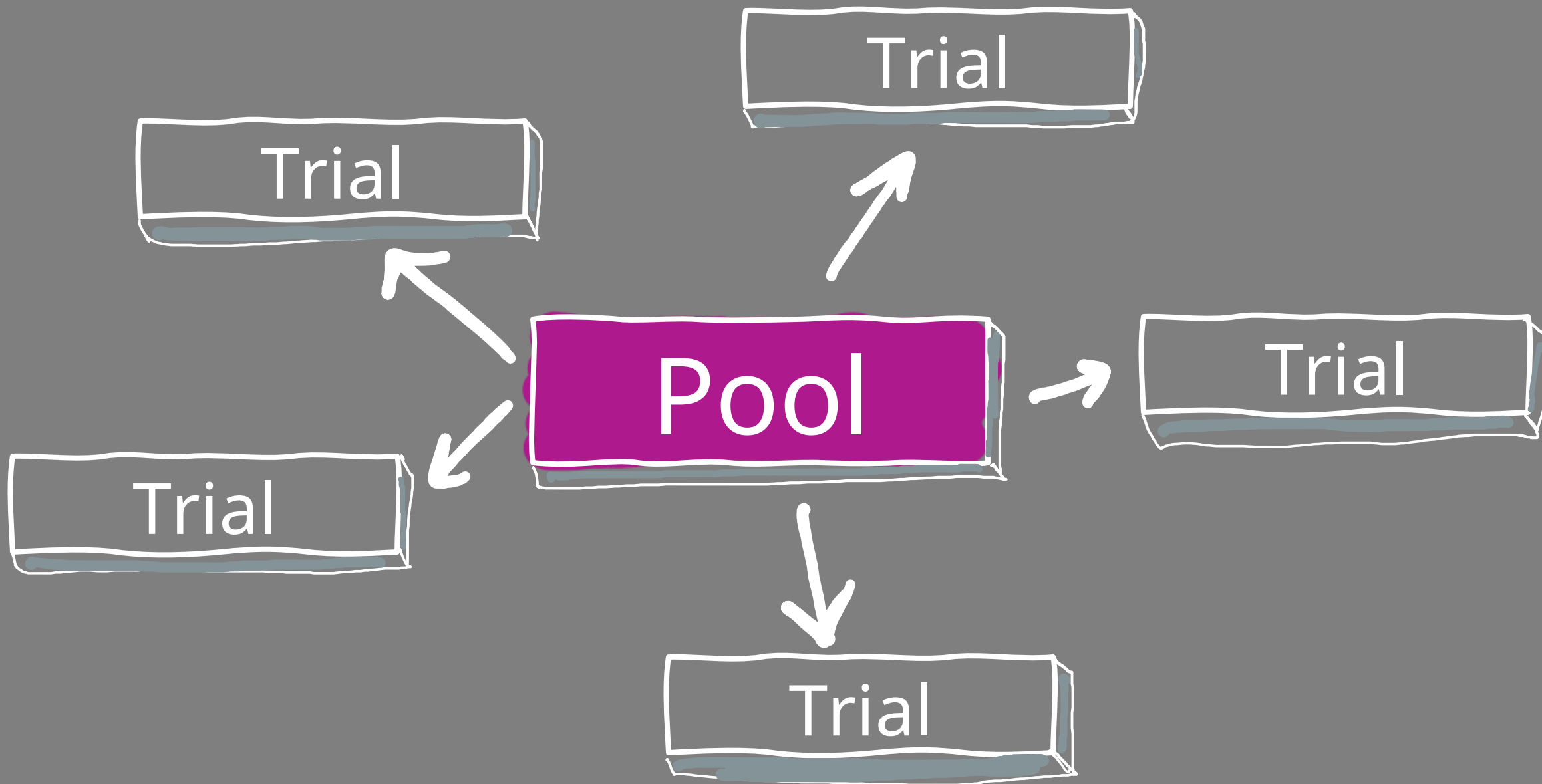


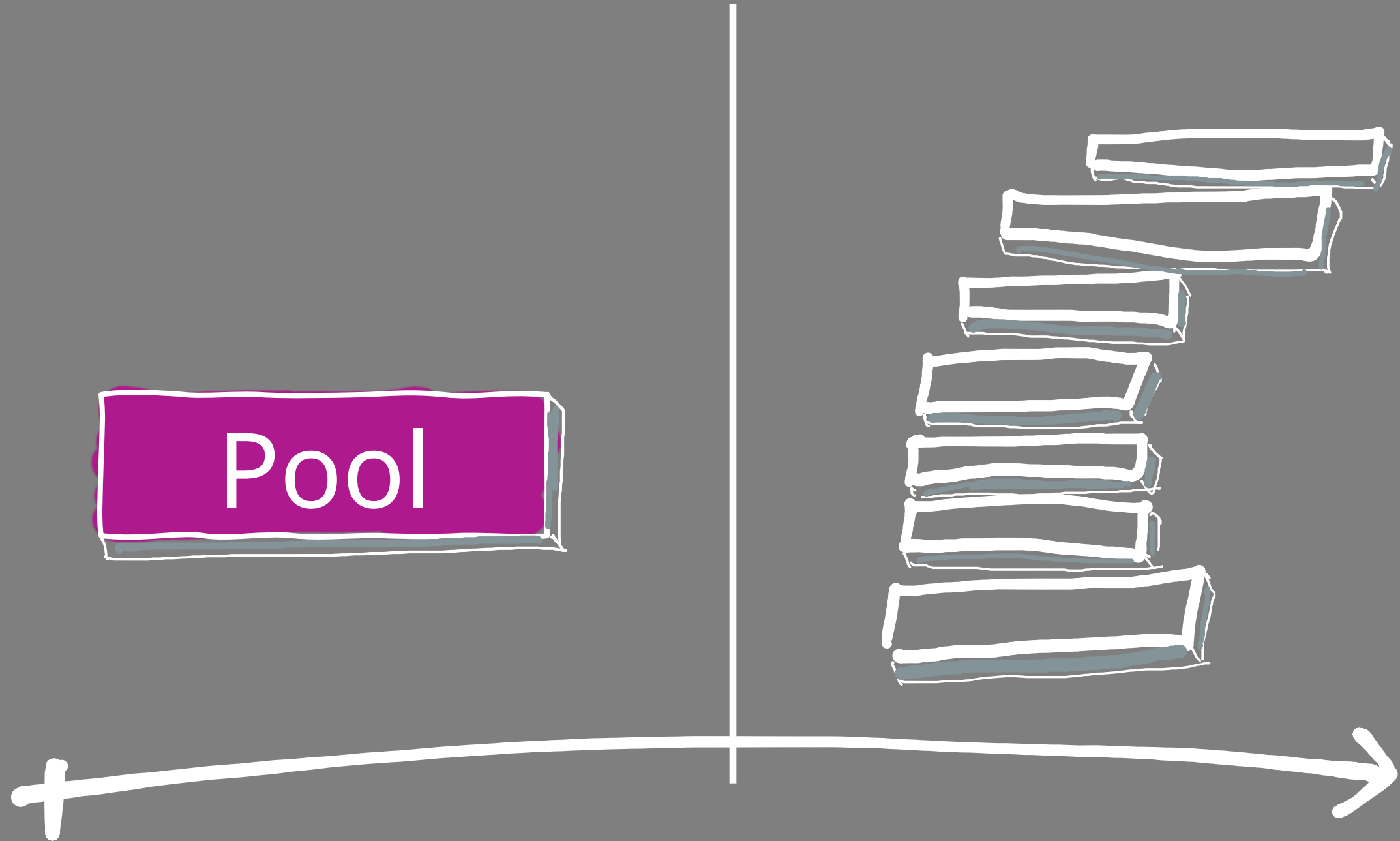
Organisation of
the team

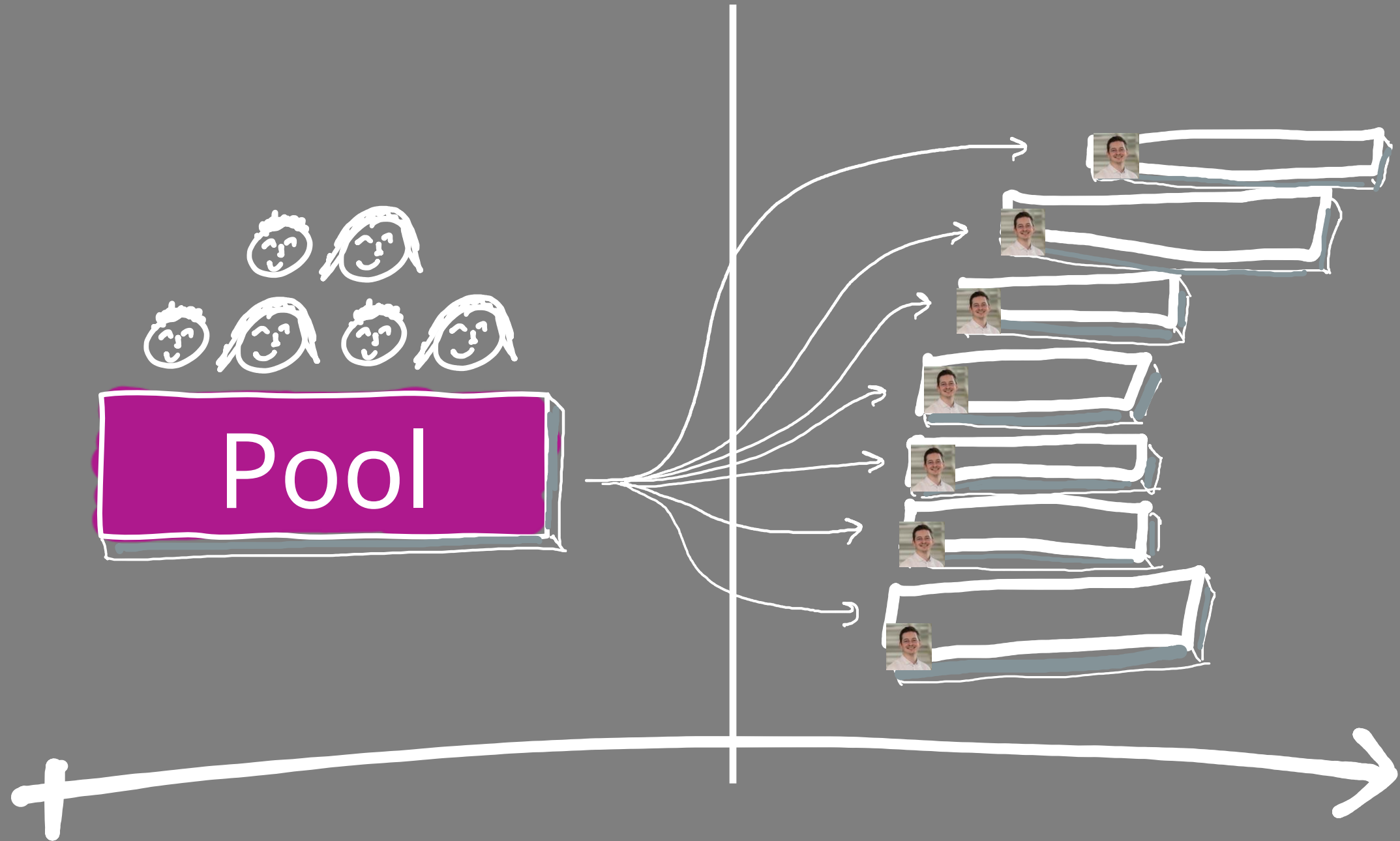


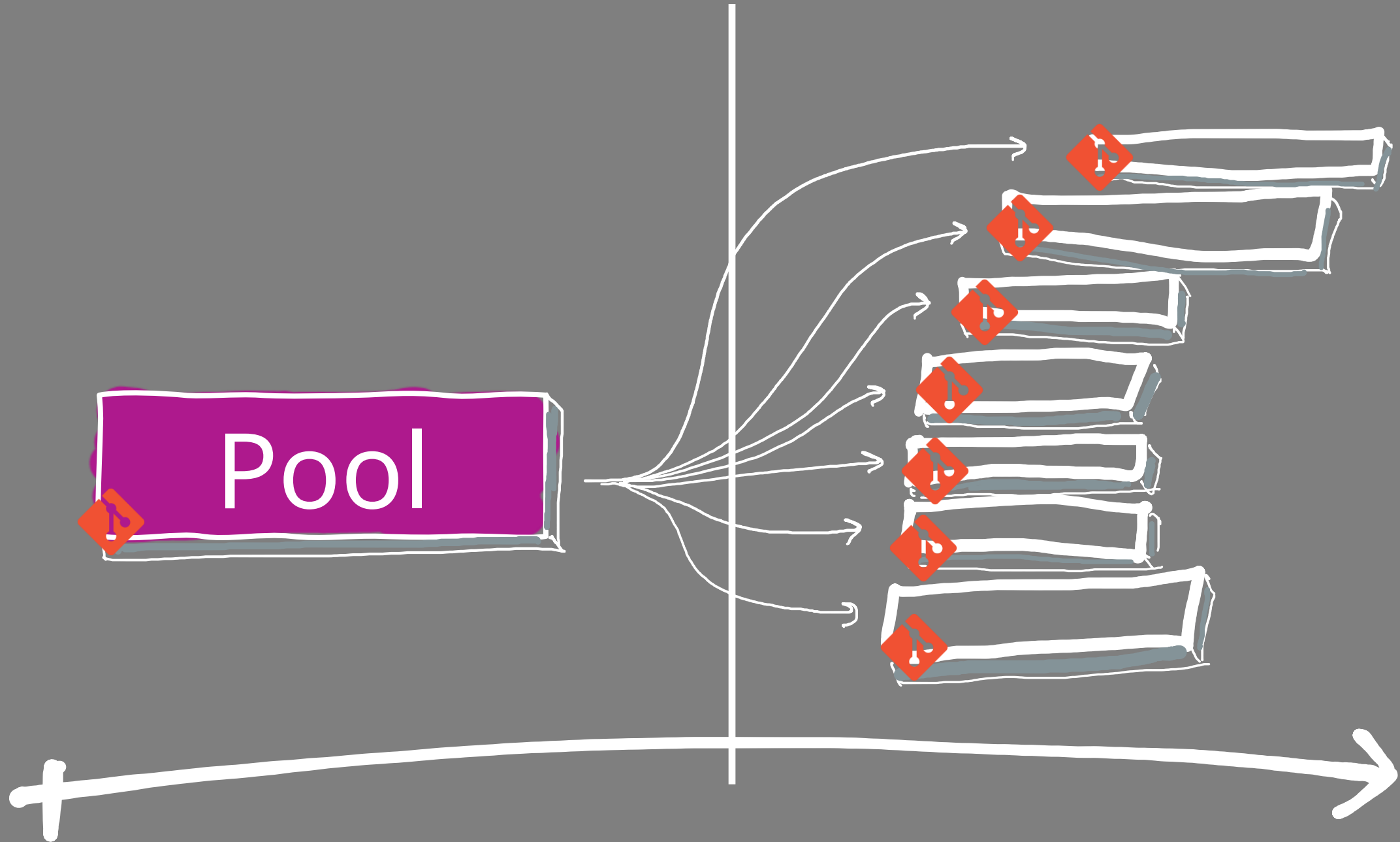














Make it work



Make it right



Make it fast



Make it work

```
    * Variables from ADAM.ADSL are attached. Only subjects in ADAM.ADSL are kept;  
data dat_3;  
    length usubjid $60.;  
    merge dat_2(in=a) adam.adsl(in=b keep=usubjid randdt trtsdt  
/*>>1234*//*>>4321*/  
    montsdt montedt  
/*<<1234*//*<<4321*/  
/*>>1234*//*>>2222*//*>>3333*/  
    bolperdt  
/*<<1234*//*<<2222*//*<<3333*/  
    saffl fasfl sex age  
  
    );  
    by usubjid;  
    if a and b;  
  
run;
```

```
* Variables from ADAM.ADSL are attached. Only subjects in ADAM.ADSL are kept;  
data dat_3;  
  length usubjid $60.;  
  merge dat 2(in=a) adam.adsl(in=b keep=usubjid randdt trtsdt  
    /*>>1234*//*>>4321*/  
    montsdt montedt  
    /*<<1234*//*<<4321*/  
    /*>>1234*//*>>2222*//*>>3333*/  
    bolperdt  
    /*<<1234*//*<<2222*//*<<3333*/  
    saffl fasfl sex age  
  
  );  
  by usubjid;  
  if a and b;  
  
run;
```

```
* Variables from ADAM.ADSL are attached. Only subjects in ADAM.ADSL are kept;  
data dat_3;  
  length usubjid $60.;  
  merge dat_2(in=a) adam.adsl(in=b keep=usubjid randdt trtsdt  
    /*>>1234*//*>>2222*//*>>3333*/  
    bolperdt  
    /*<<1234*//*<<2222*//*<<3333*/  
    saffl fasfl sex age  
  
  );  
  by usubjid;  
  if a and b;  
  
run;
```



Make it right

metaslice()

ADaM metadata

include_in_trial	include_in_submission	deliverable	Phase_1	Phase_2	Phase_3	table	column	label	or
Y	Y				Y	ADSL	BOLPERDT	Bolus Period Start Date	
Y	Y				Y	ADSL	BOLPERFL	Bolus Period Flag	
Y	Y		Y	Y	Y	ADSL	RFXSTDTC	Date/Time of First Study Treatment	
Y	Y	-1234			Y	ADSL	TRTSDT	Date of First Exposure to Treatment	
Y	Y	1234	Y	Y		ADSL	TRTSDT	Date of First Exposure to Treatment	
Y	Y		Y	Y	Y	ADSL	TRTSDT	Date of First Exposure	

metaslice()

External data

Classification metadata

MedDRA queries

metaslice()

TFL metadata

metaslice()

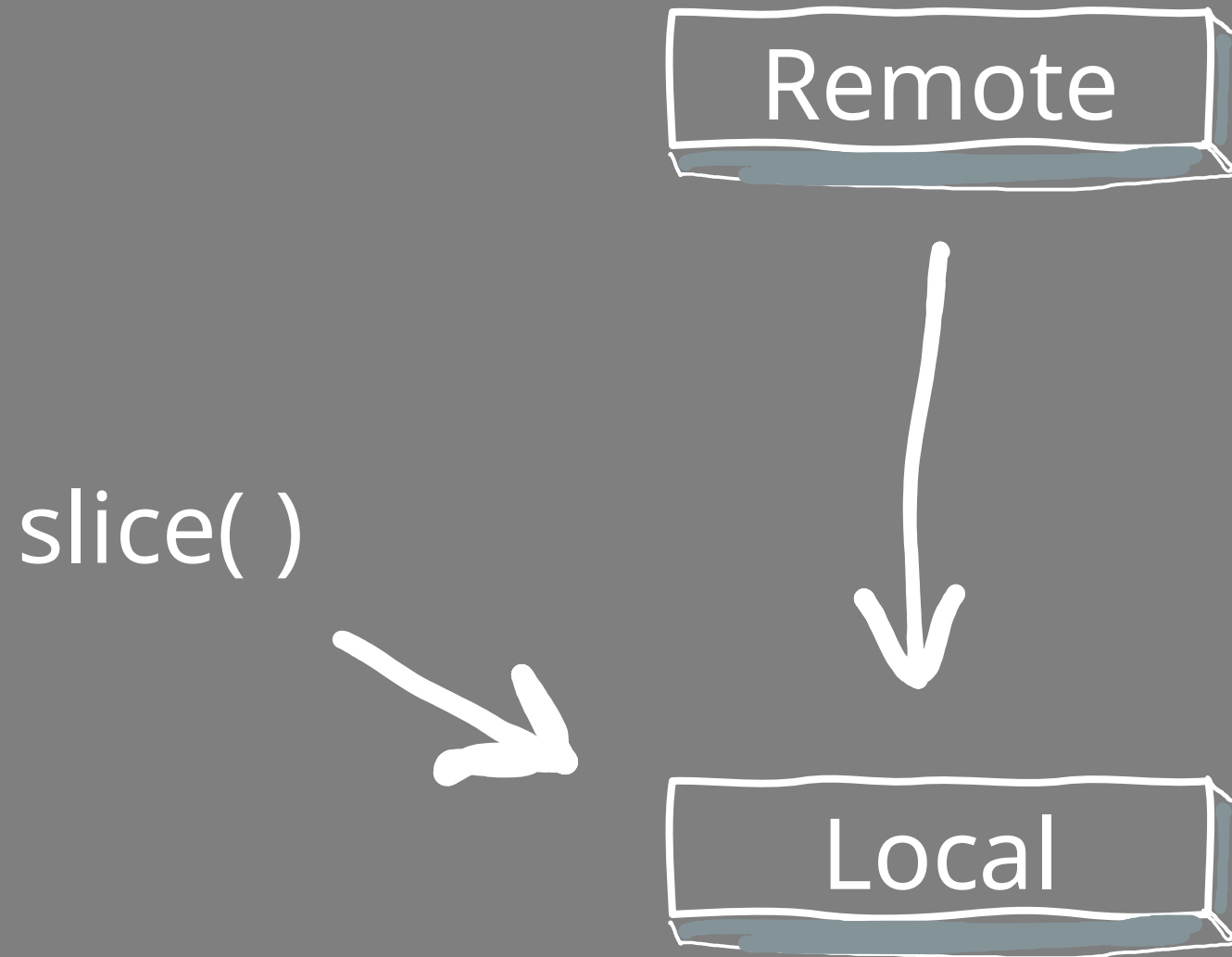
renv



Recreates environment



Commits to trial repo



```
* Variables from ADAM.ADSL are attached. Only subjects in ADAM.ADSL are kept;  
data dat_3;  
  length usubjid $60.;  
  merge dat 2(in=a) adam.adsl(in=b keep=usubjid randdt trtsdt  
    /*>>1234*//*>>4321*/  
    montsdt montedt  
    /*<<1234*//*<<4321*/  
    /*>>1234*//*>>2222*//*>>3333*/  
    bolperdt  
    /*<<1234*//*<<2222*//*<<3333*/  
    saffl fasfl sex age  
  
  );  
  by usubjid;  
  if a and b;  
  
run;
```

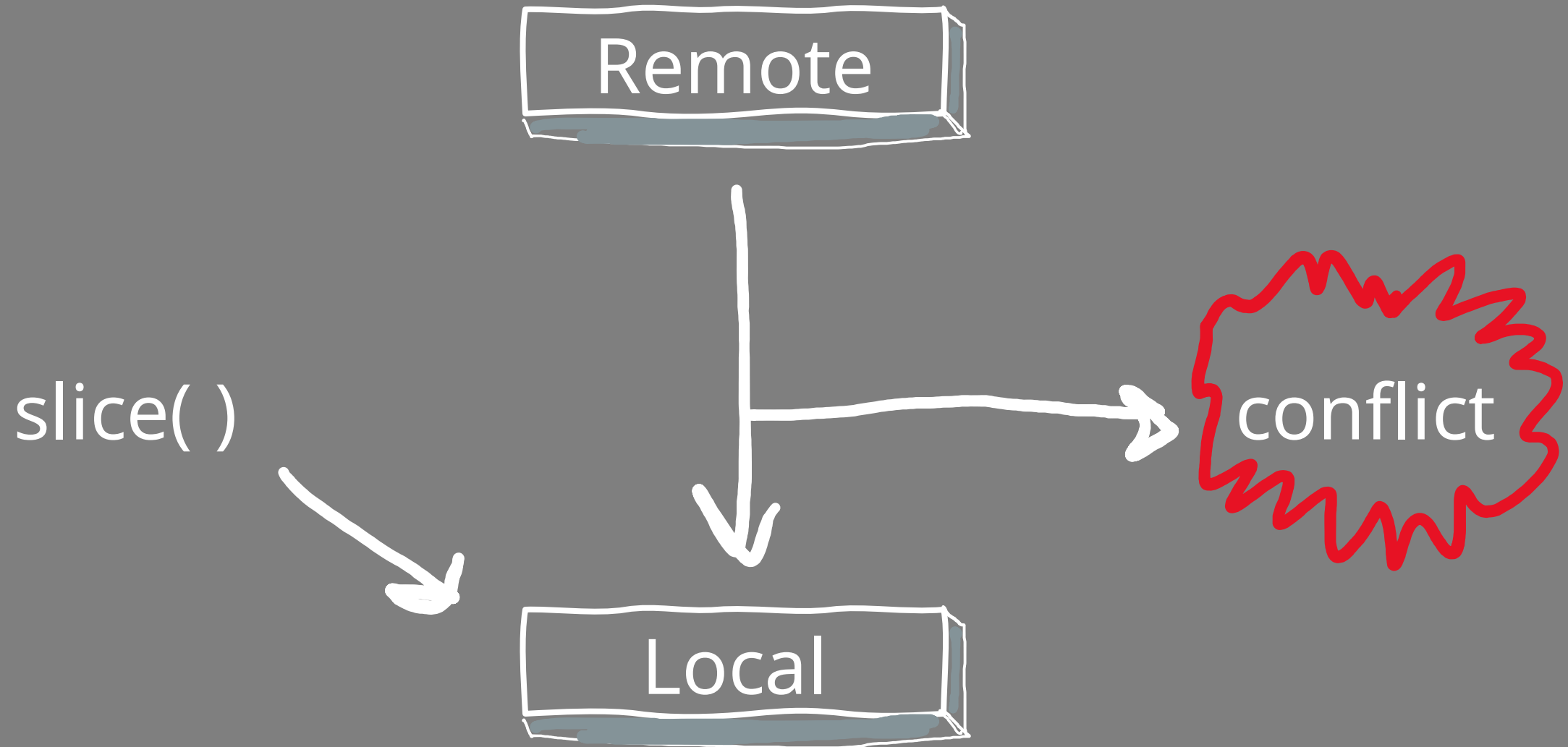
```
* Variables from ADAM.ADSL are attached. Only subjects in ADAM.ADSL are kept;
data dat_3;
    length usubjid $60.;
    merge dat_2(in=a) adam.adsl(in=b keep=usubjid randdt trtsdt
/*>>1234*//*>>4321*/
    montsdt montedt
    super duper extra many changes
    made to these specific trials
/*<<1234*//*<<4321*/
/*>>1234*//*>>2222*//*>>3333*/
    bolperdt
/*<<1234*//*<<2222*//*<<3333*/
    safll fasll sex age

);
by usubjid;
if a and b;

run;
```

```
* Variables from ADAM.ADSL are attached. Only subjects in ADAM.ADSL are kept;  
data dat_3;  
  length usubjid $60.;  
  merge dat_2(in=a) adam.adsl(in=b keep=usubjid randdt trtsdt  
    /*>>1234*//*>>2222*//*>>3333*/  
    bolperdt  
    /*<<1234*//*<<2222*//*<<3333*/  
    saffl fasfl sex age  
  
  );  
  by usubjid;  
  if a and b;  
  
run;
```

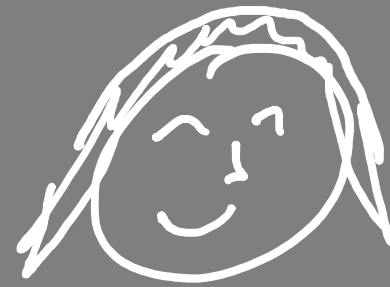
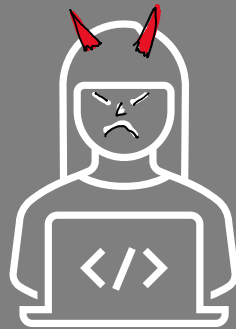
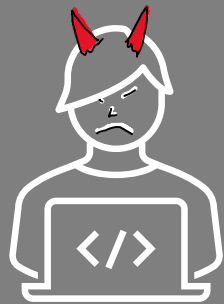
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	AUTO: adamprog re-generated from pool. b25e9954  AIKP (Ari Siggaard Knoph) 27 Apr 2022 at 22:28
	AUTO: parprog/fppsub re-generated from pool. 8cb6a582  AIKP (Ari Siggaard Knoph) 27 Apr 2022 at 15:46
	AUTO: parprog/statprog re-generated from pool. a549142b  AIKP (Ari Siggaard Knoph) 27 Apr 2022 at 15:46
	AUTO: parprog/adamprog re-generated from pool. 92eb3d22  AIKP (Ari Siggaard Knoph) 27 Apr 2022 at 15:46
	AUTO: statprog re-generated from pool. 0acaff67  AIKP (Ari Siggaard Knoph) 27 Apr 2022 at 15:46





A hand-drawn diagram on a dark gray background. A white line starts from the left, goes up, then right, then down, and finally continues as a long arrow pointing to the right. The text '*Path of least' is written in white, bold, sans-serif font above the arrow, and '*resistance' is written below it. The asterisks are positioned at the start of the path and the arrow respectively.

*Path of least
*resistance



SOP



Document
your
process

Complete process



Error!

Cannot complete process without documentation!

Try again



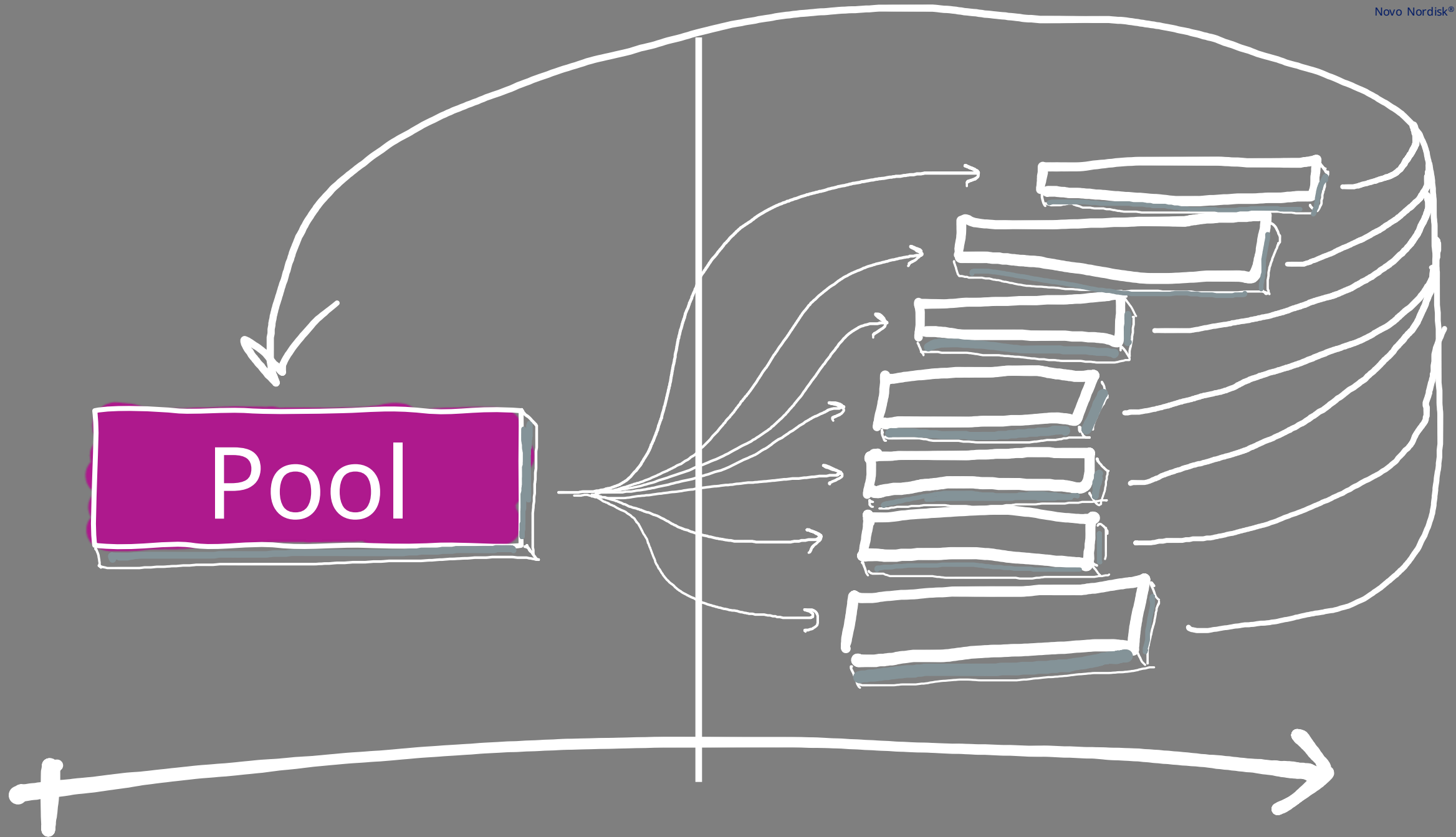
my_stupid_sop_documentation_final.pdf



my_stupid_sop_documentation_final_FINAL.pdf



Make it fast



Pools are in

Thank you!