



# How R pharma?

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OS01 – PHUSE EU Connect 2024



# What is pharmaverse?





SDTM

ADaM

TFL

Shiny

eSub

Utilities



# What is pharmaverse?

Supported  
by





# Pharmaverse collaborates



SDTM

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Utilities

- PHUSE Supported
- R/pharma
- R consortium
- CDISC
- (Authorities)



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**pharmaverse:**  
*Breaking boundaries through  
open-source collaboration*

*Presented to Office of Computational Sciences, US  
FDA*



Supported  
by  
**phuse**



# The survey



SDTM

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Shiny

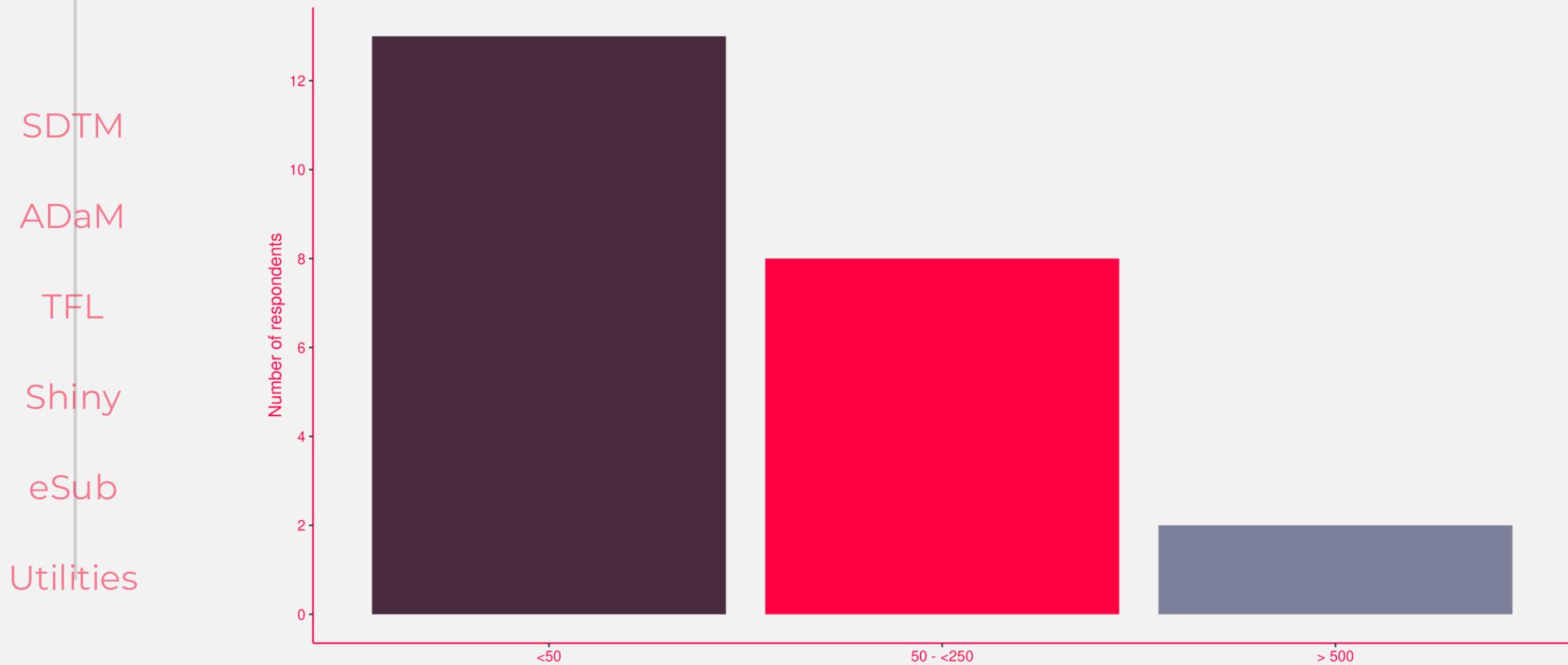
eSub

Utilities

- Large representation of top 20 pharma
- Usage of R and pharmaverse packages
- Repeated yearly

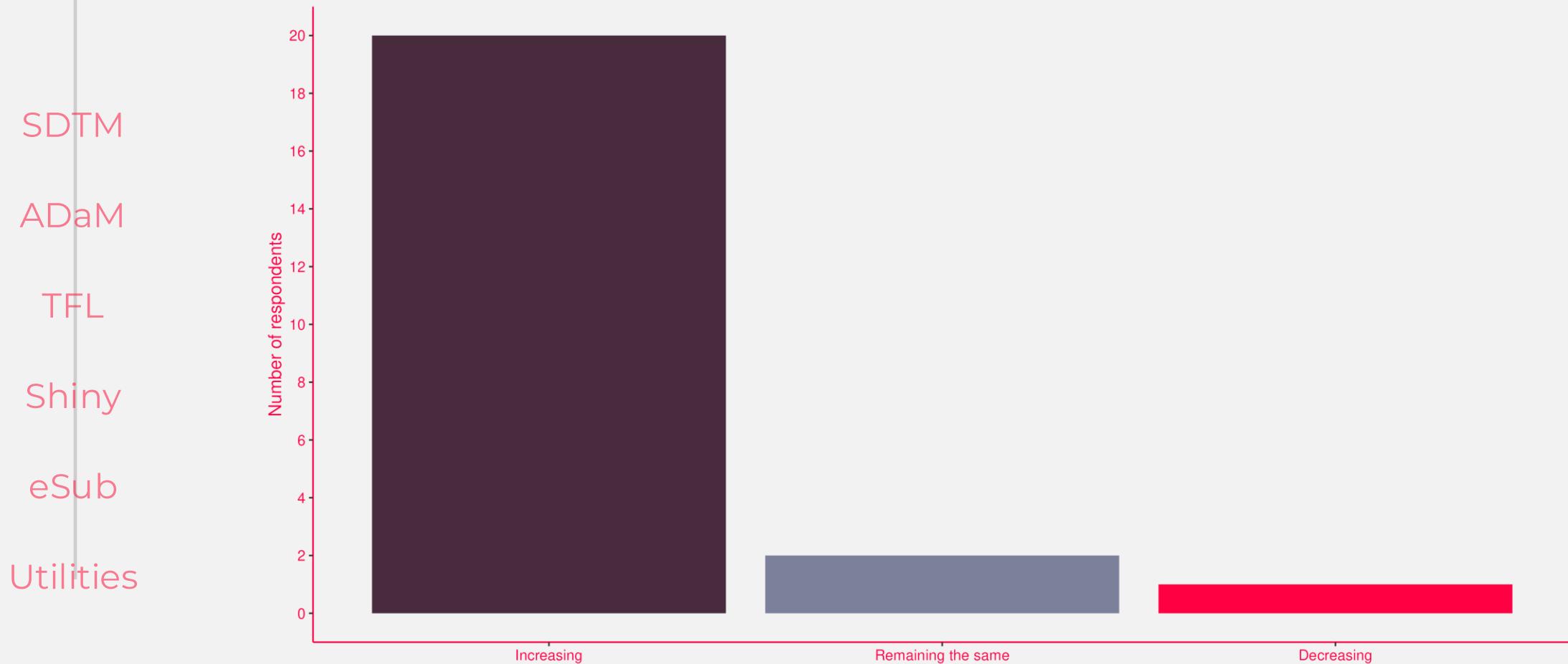


# Number of R users



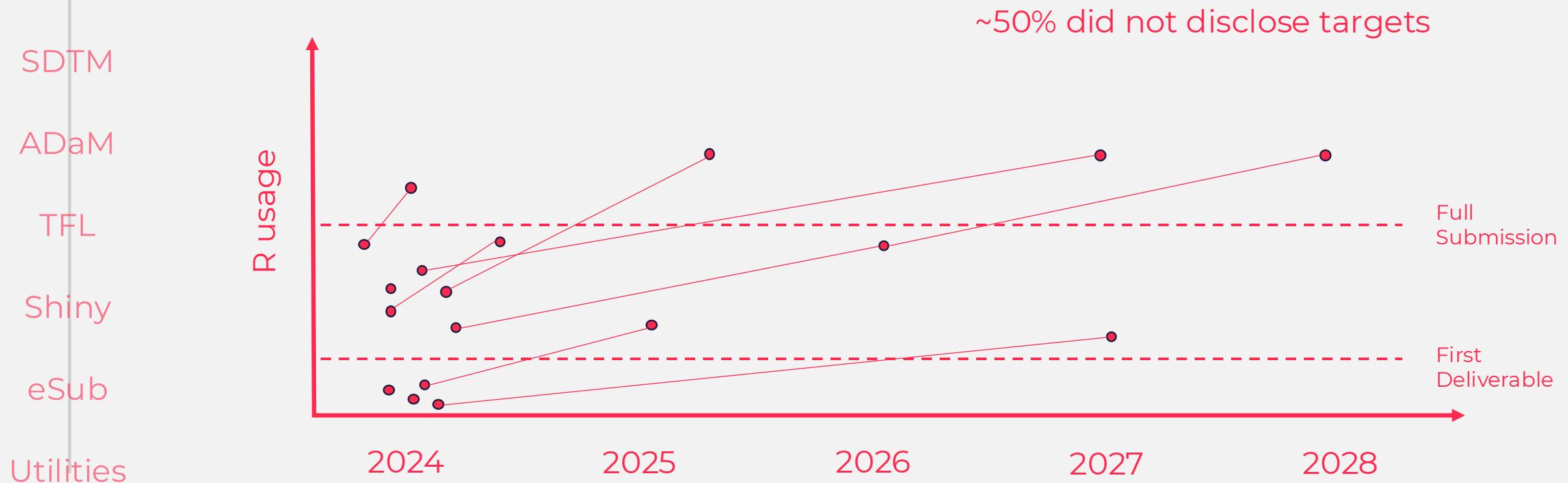


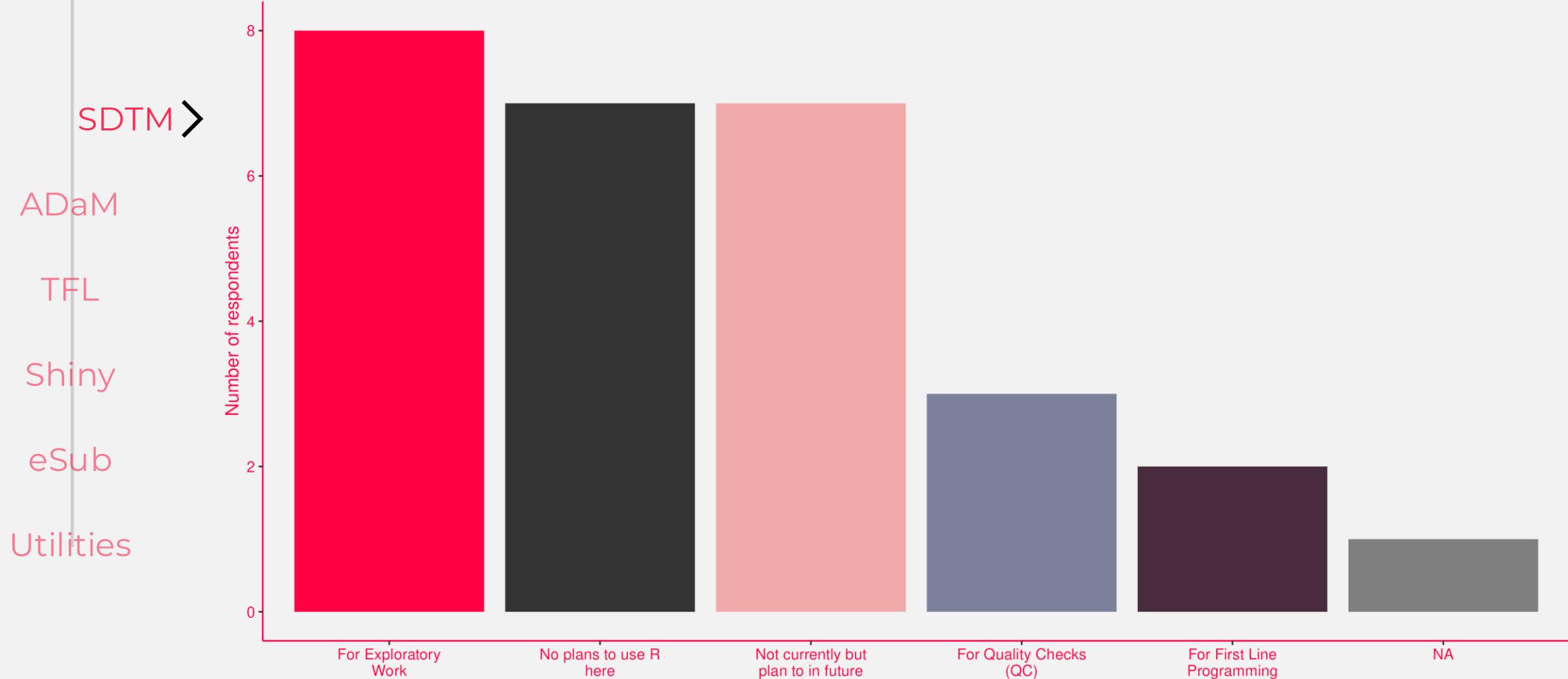
# Usage of R

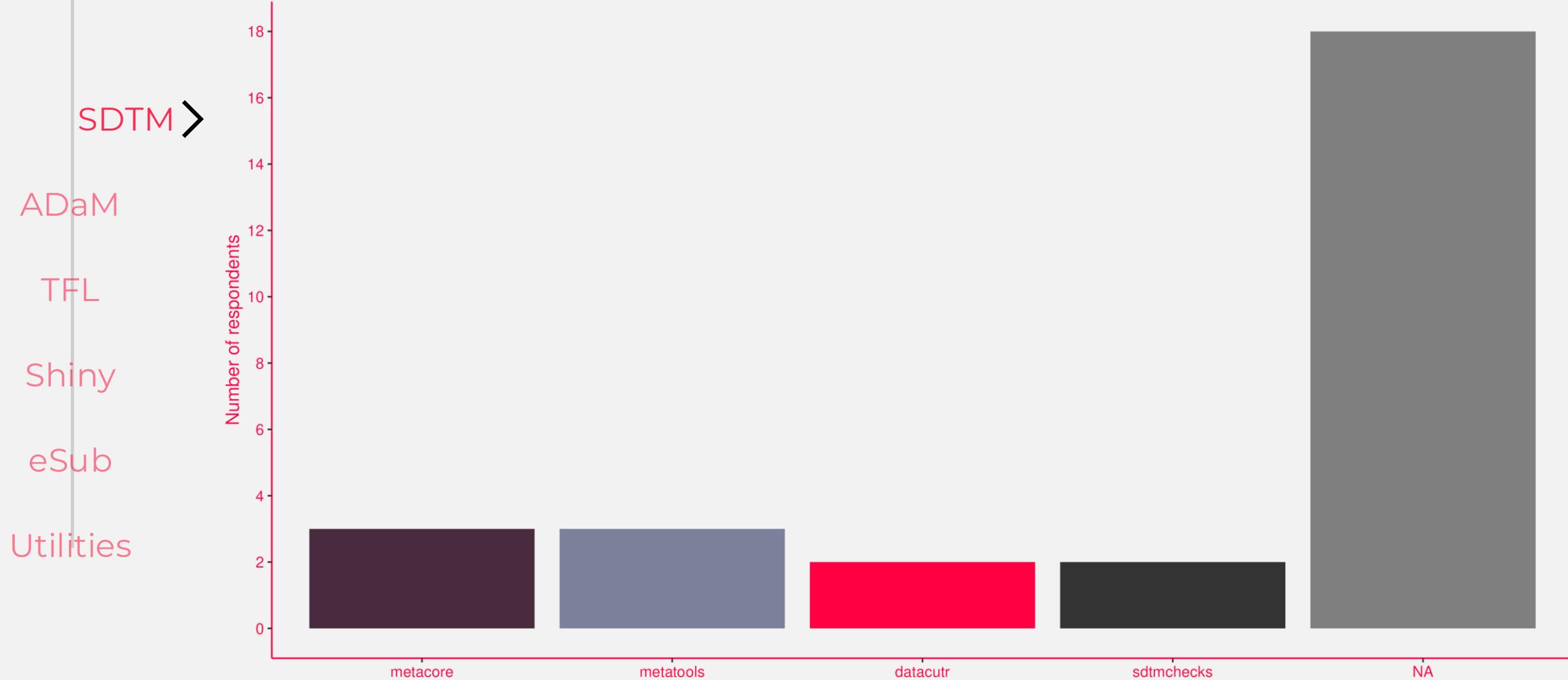




# Targets for R









# SDTM.OAK

SDTM >

ADaM

TFL

Shiny

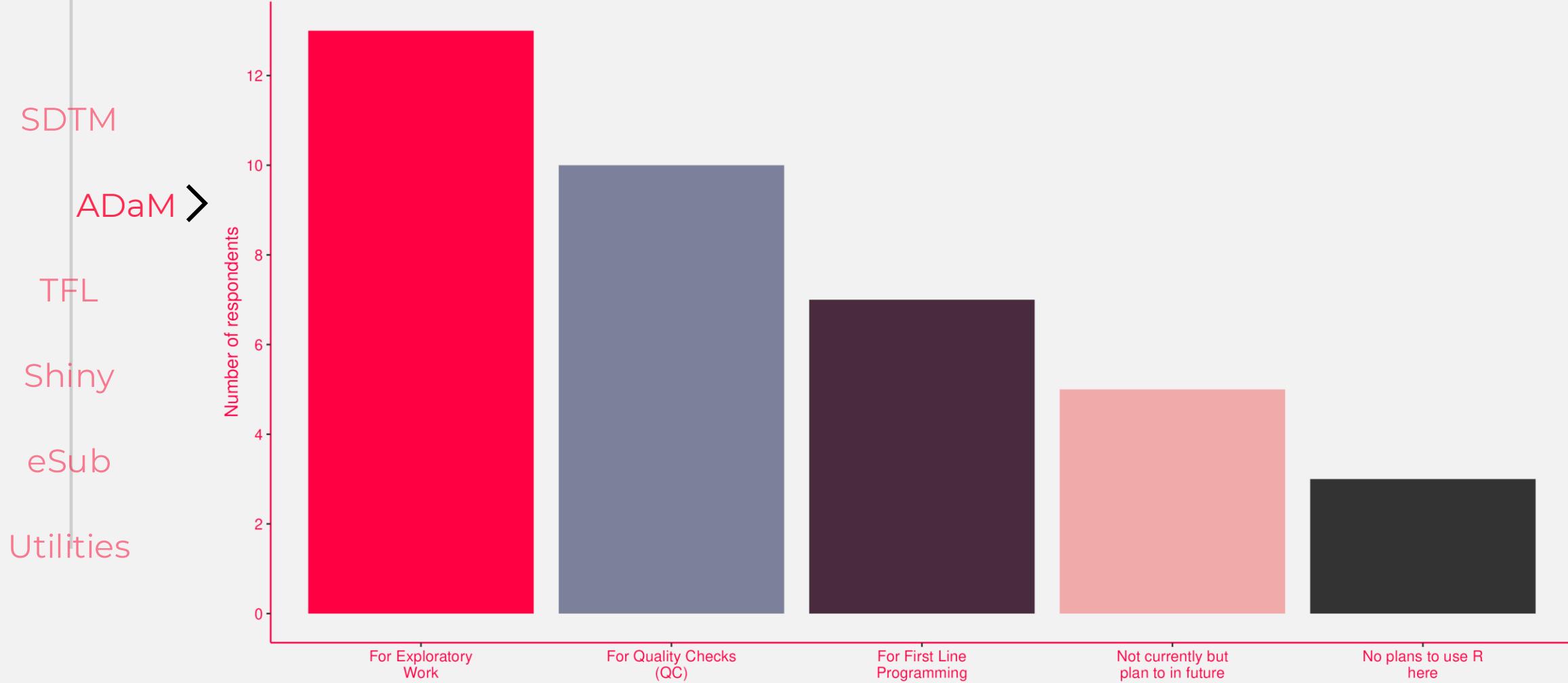
eSub

Utilities



- CDASH to SDTM
- EDC and Data Standard agnostic
- Modular and built for automation







SDTM

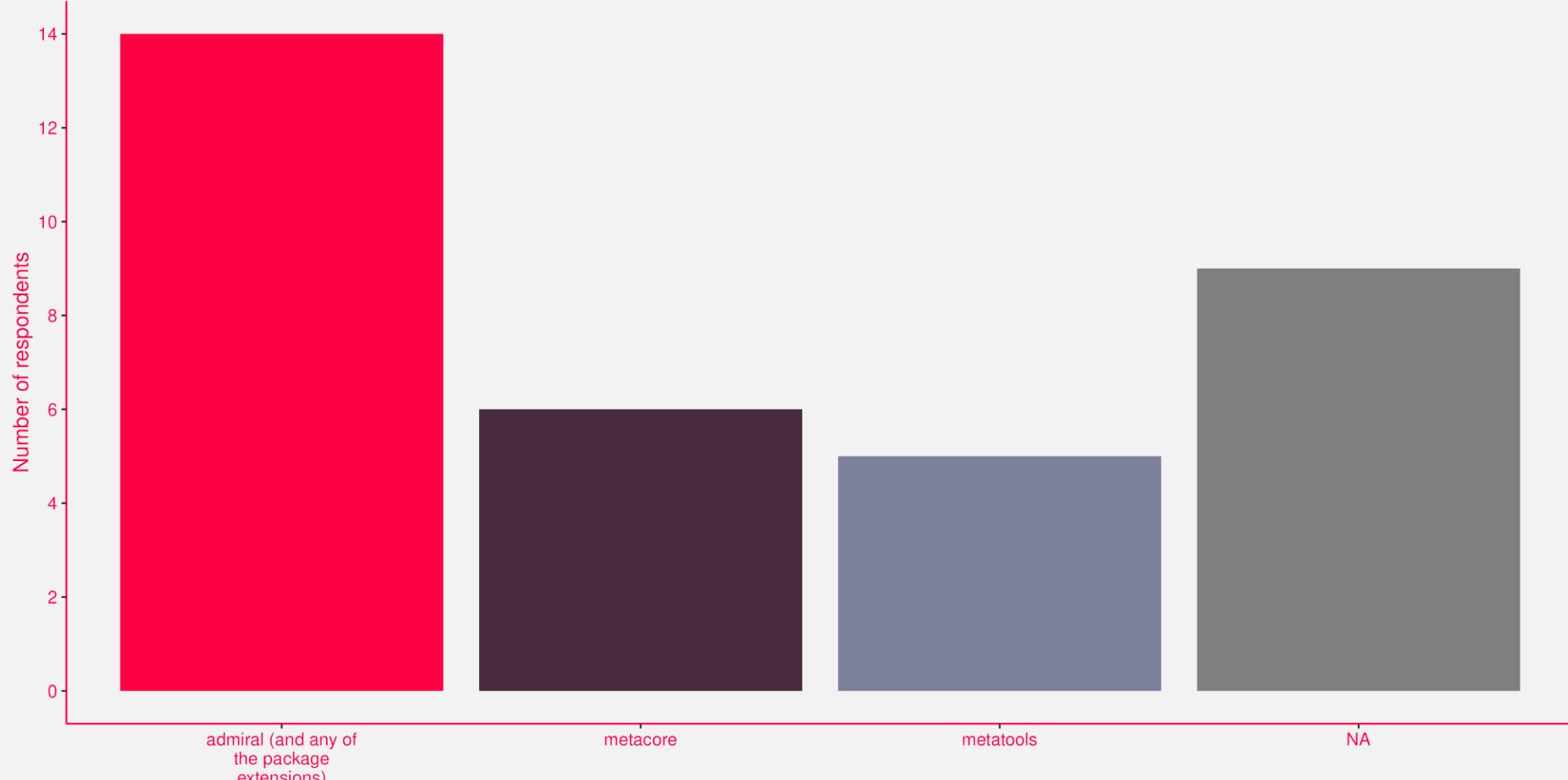
ADaM >

TFL

Shiny

eSub

Utilities





# admiral family

SDTM

ADaM >

TFL

Shiny

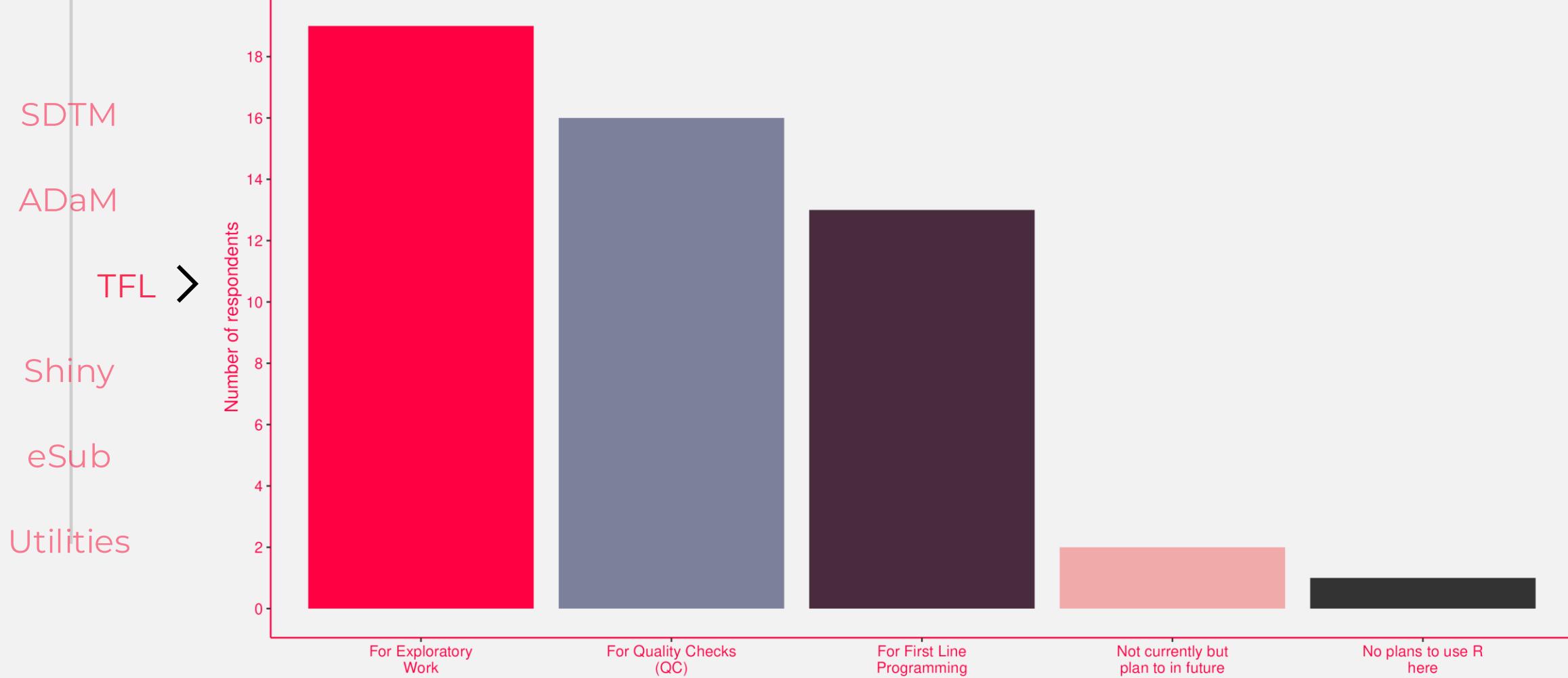
eSub

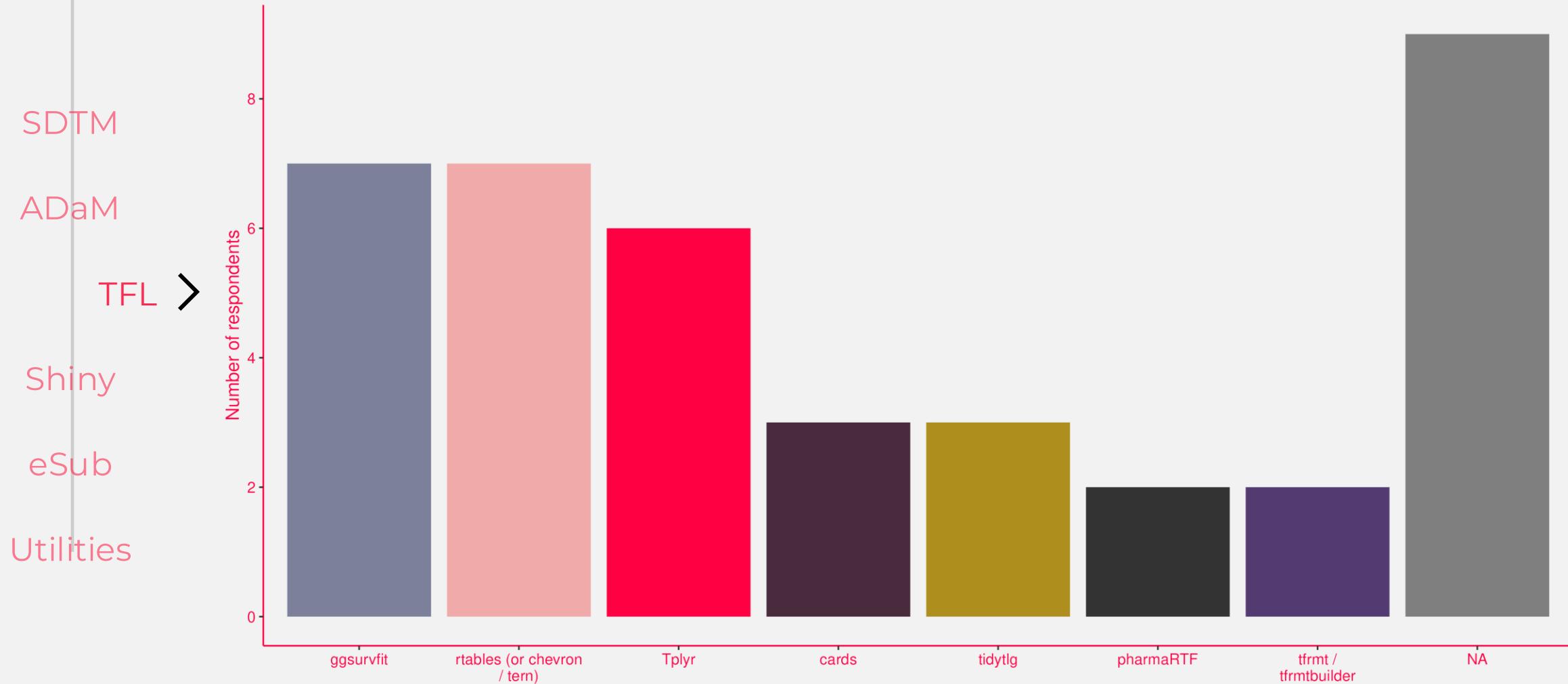
Utilities



Bristol Myers Squibb™









# ARDS

SDTM

ADaM

TFL >

Shiny

eSub

Utilities





SDTM

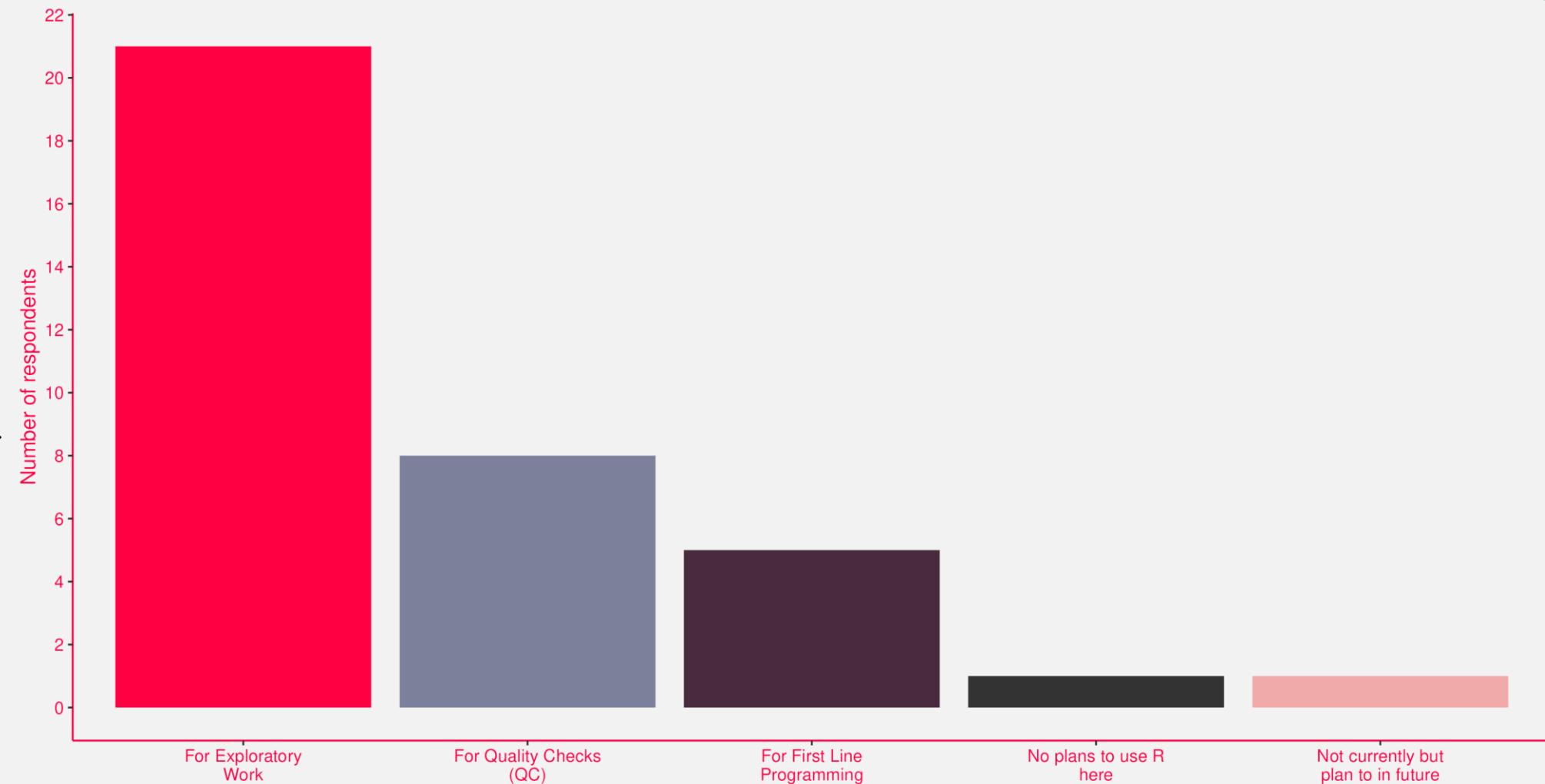
ADaM

TFL

Shiny >

eSub

Utilities





SDTM

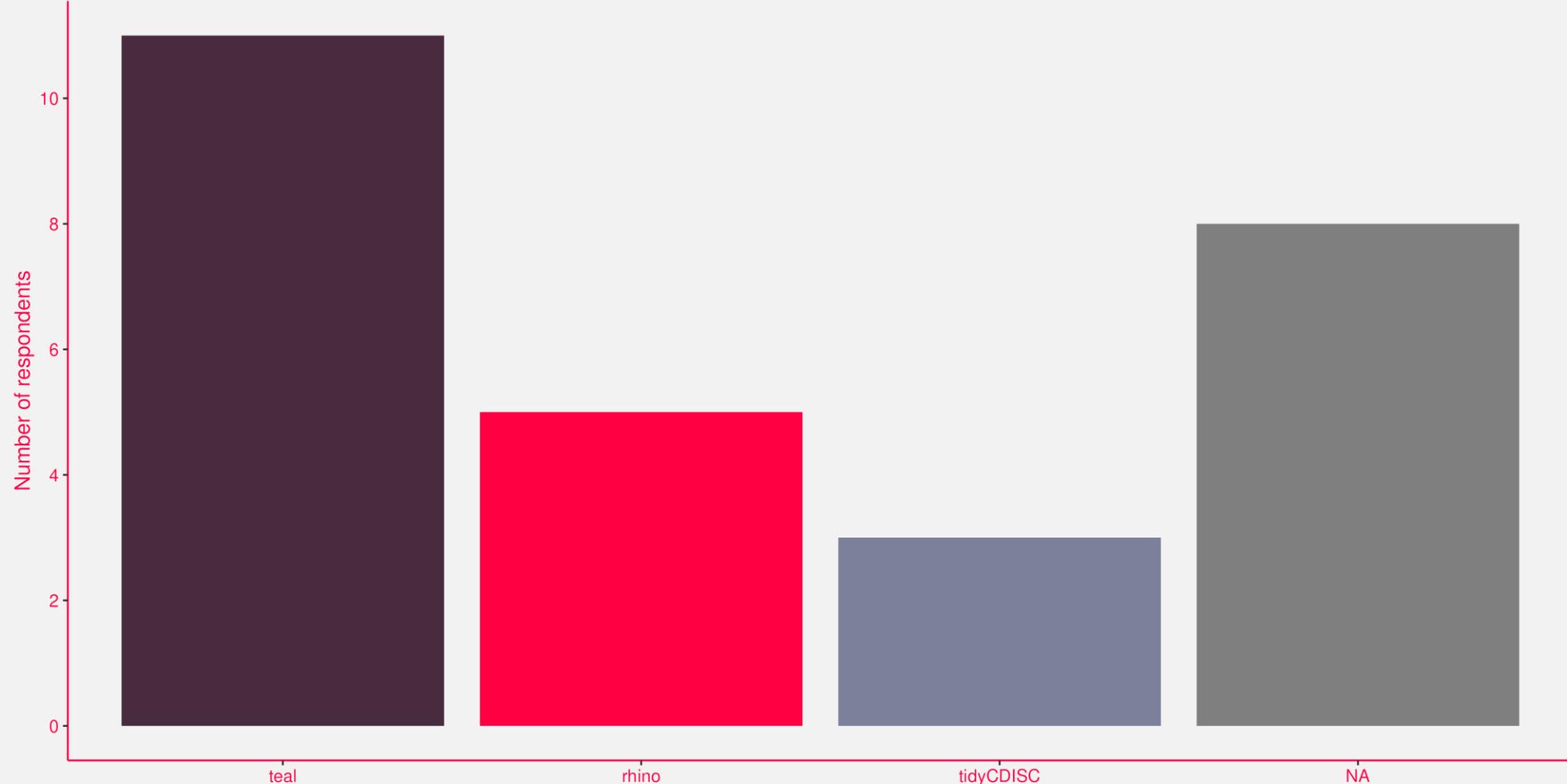
ADaM

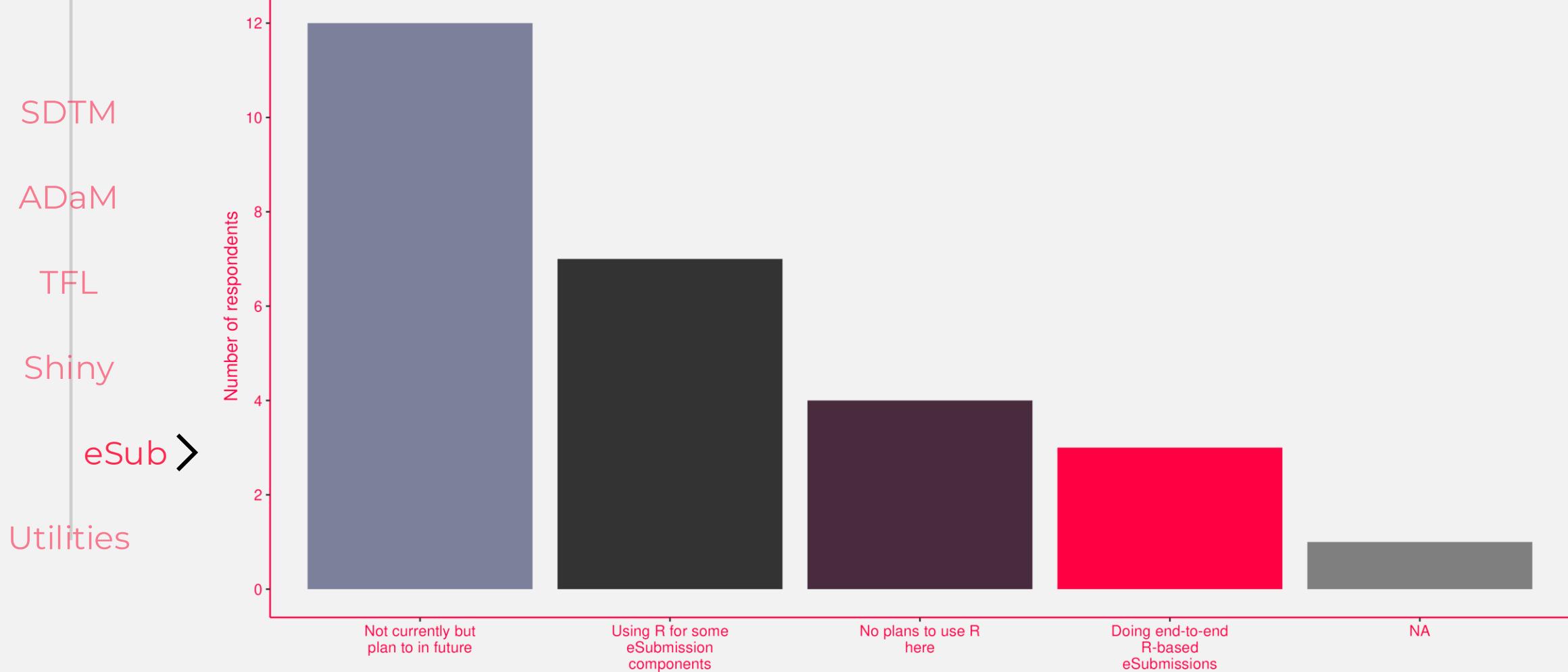
TFL

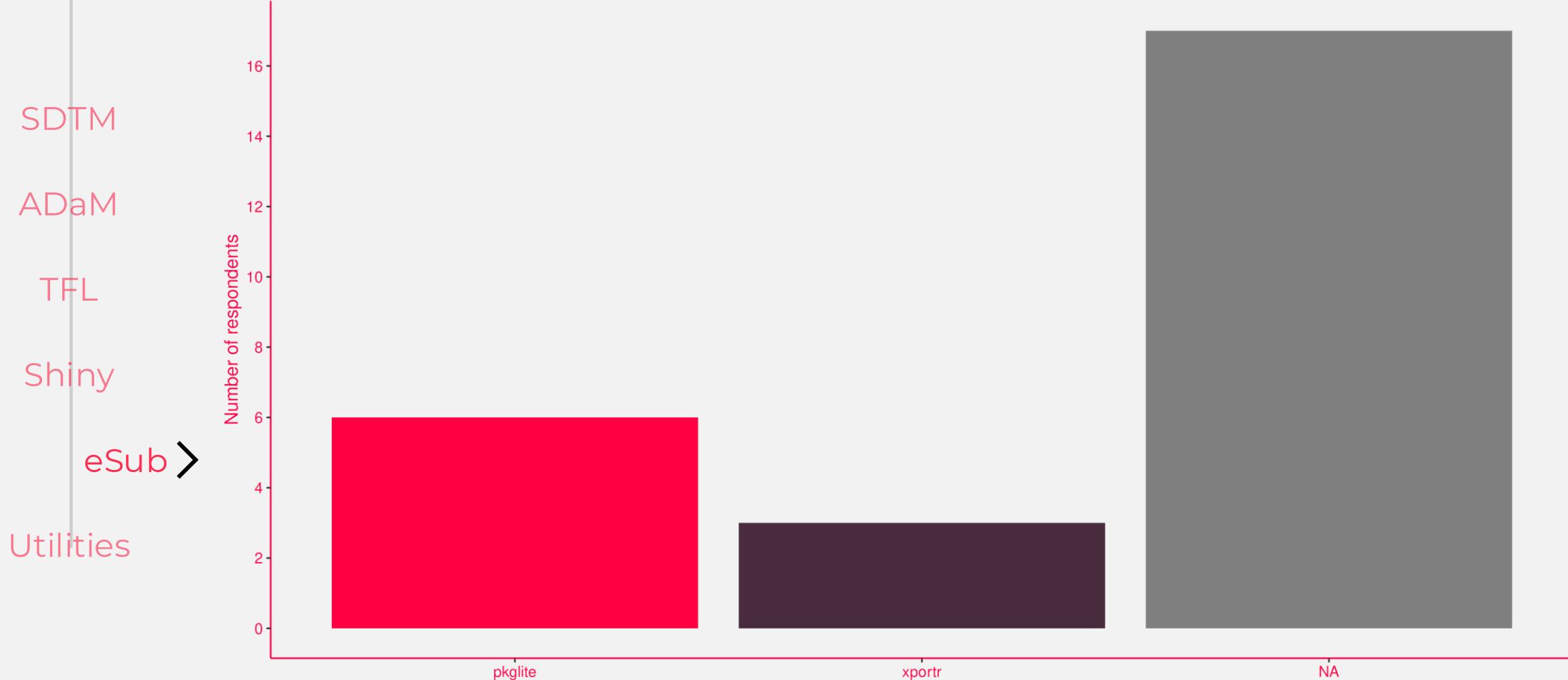
Shiny >

eSub

Utilities









SDTM

ADaM

TFL

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eSub >

Utilities



Pilot 1: TFL

Pilot 2: Shiny application

Pilot 3: ADaM + TFL

Pilot 4: Webassembly / Container





SDTM

ADaM

TFL

Shiny

eSub >

Utilities



- Read/Write data in datasetJSON format
- Great example of rapid prototyping using pharmaverse infrastructure



# Submission status

SDTM

ADaM

TFL

Shiny

eSub >

Utilities





SDTM

ADaM >

TFL

Shiny

eSub

Utilities

# Submissions



## The Programming Strategy

End-to-end in R submission - using primarily open source packages from pharmaverse



**SDTM**



**ADaM**



**TLGs**



**Proprietary**

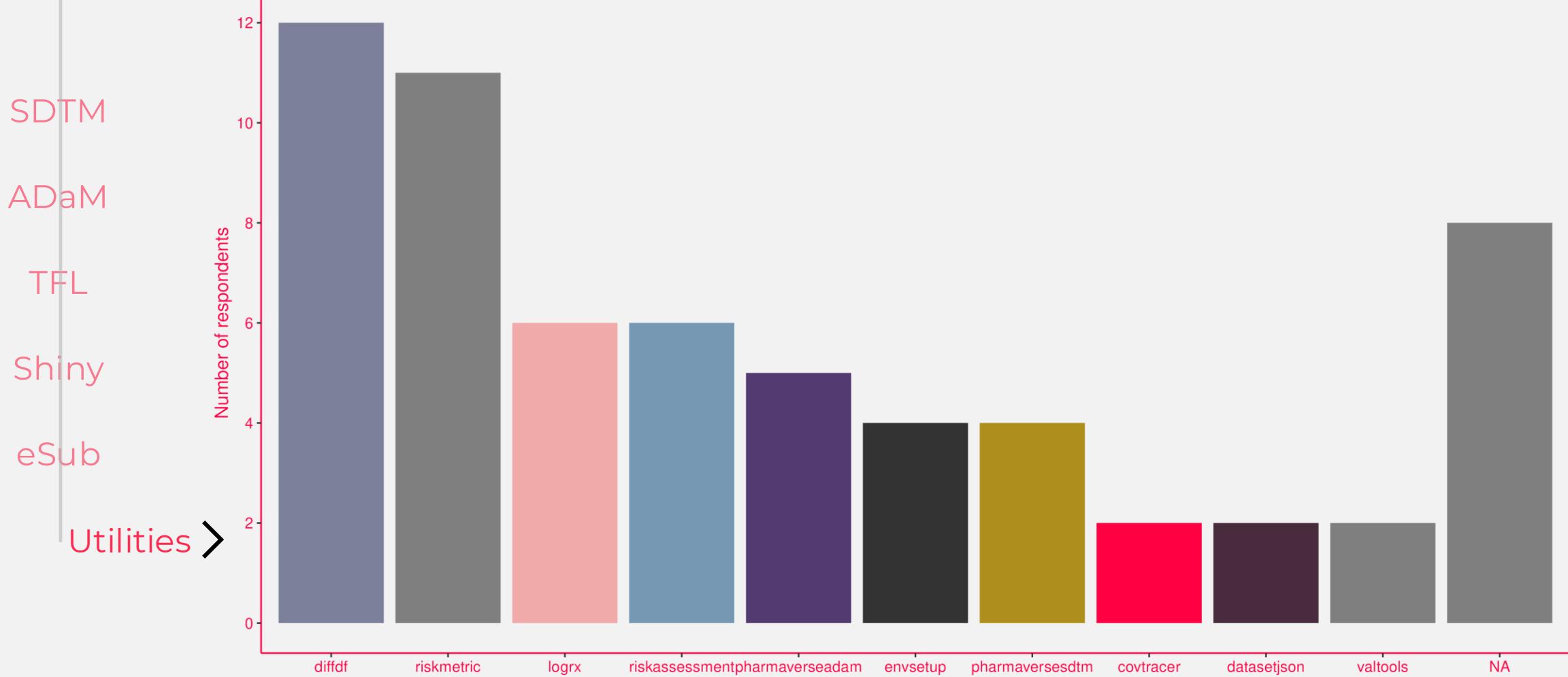


**Readable code**



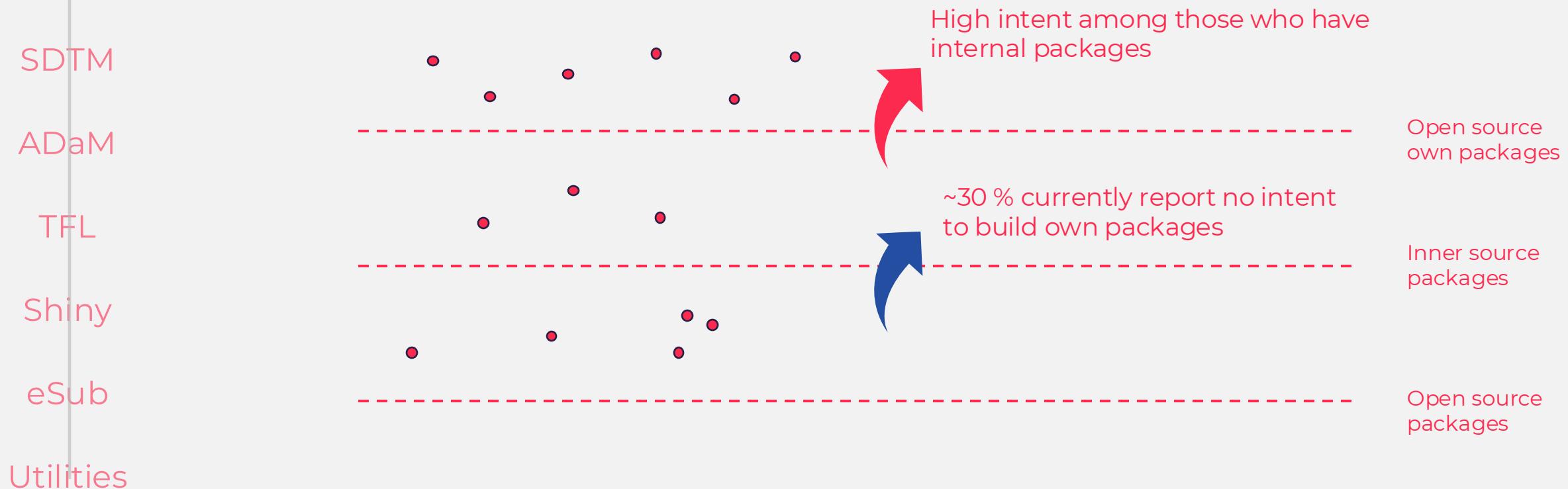
13

26





# Open/Inner source R packages





# Pharmaverse – Why collaborate?



- Streamlined workflows and consistent quality across clinical reports/submissions
- Facilitate regulatory compliance through standardized packages
- Reduce redundant efforts, increasing efficiency and reducing costs
- Encourage innovation and rapid problem-solving through shared knowledge and resources



# Call to action



- Your barriers
- Your feedback
- Your future



[www.pharmaverse.org](http://www.pharmaverse.org)

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