

R for submission – Experiences from the R consortium working group

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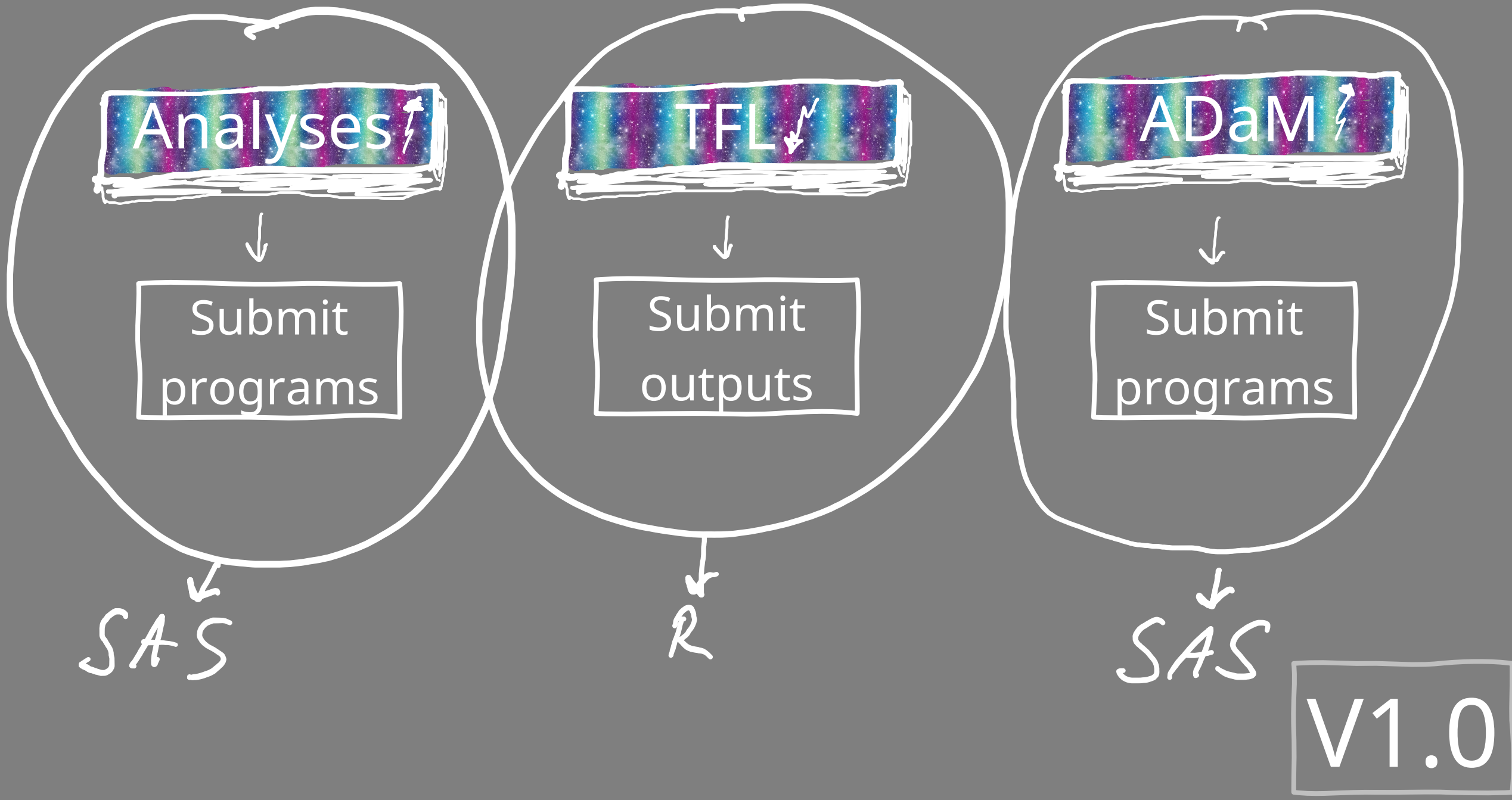
Statistical Programming Specialist

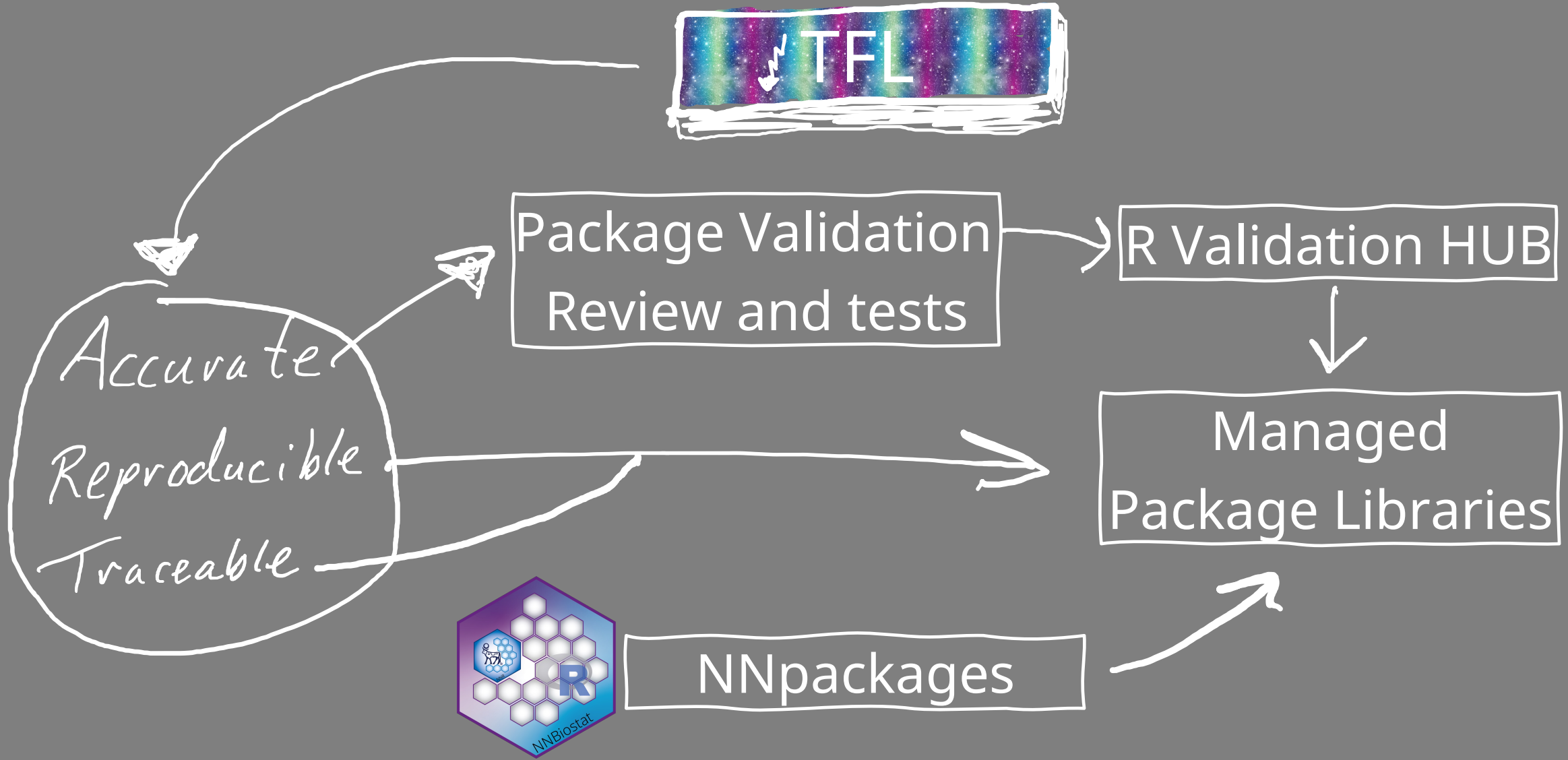
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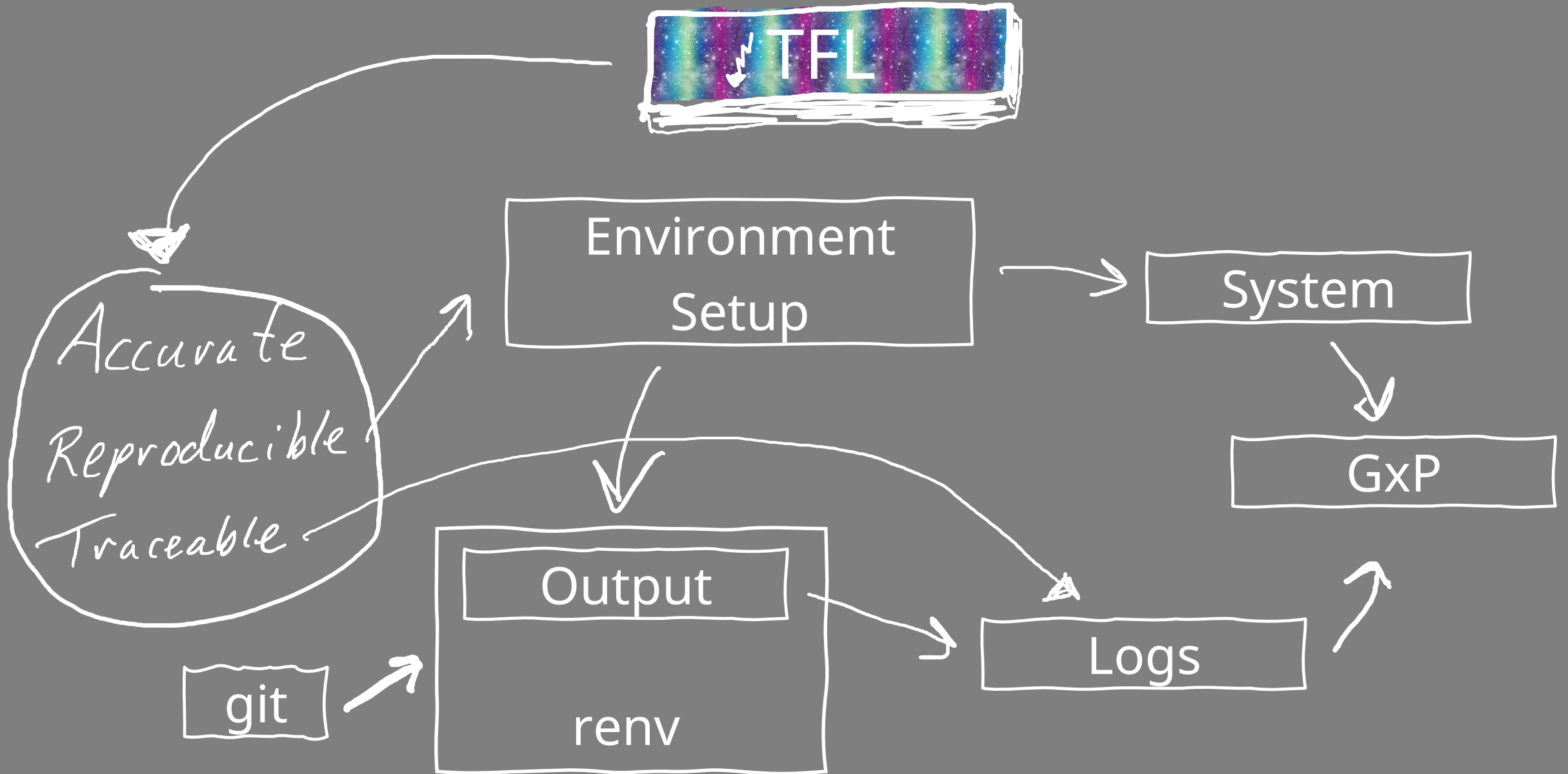
See if it was possible

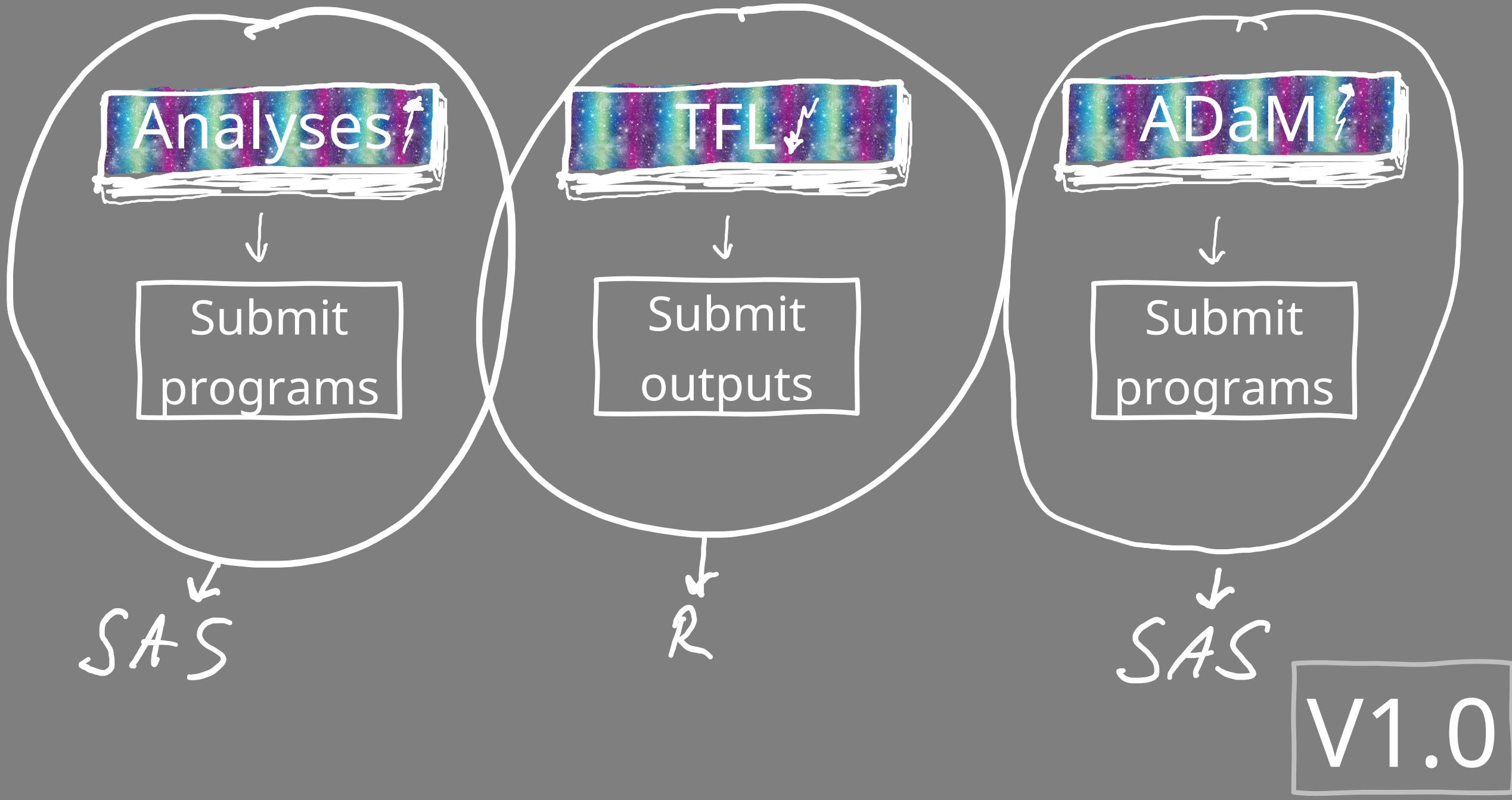
Prove it was possible

Prove that it's safe

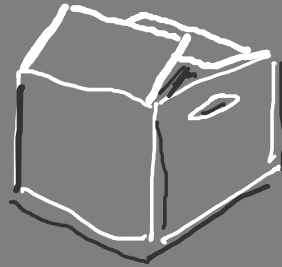




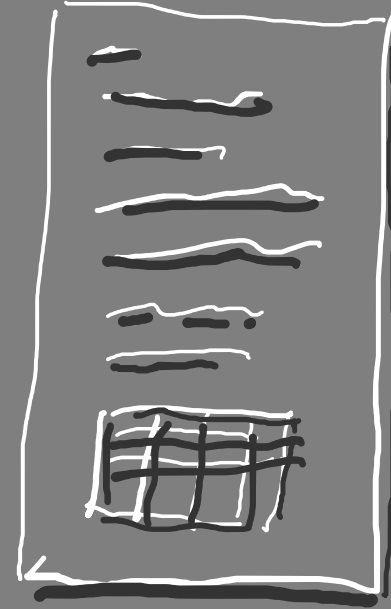




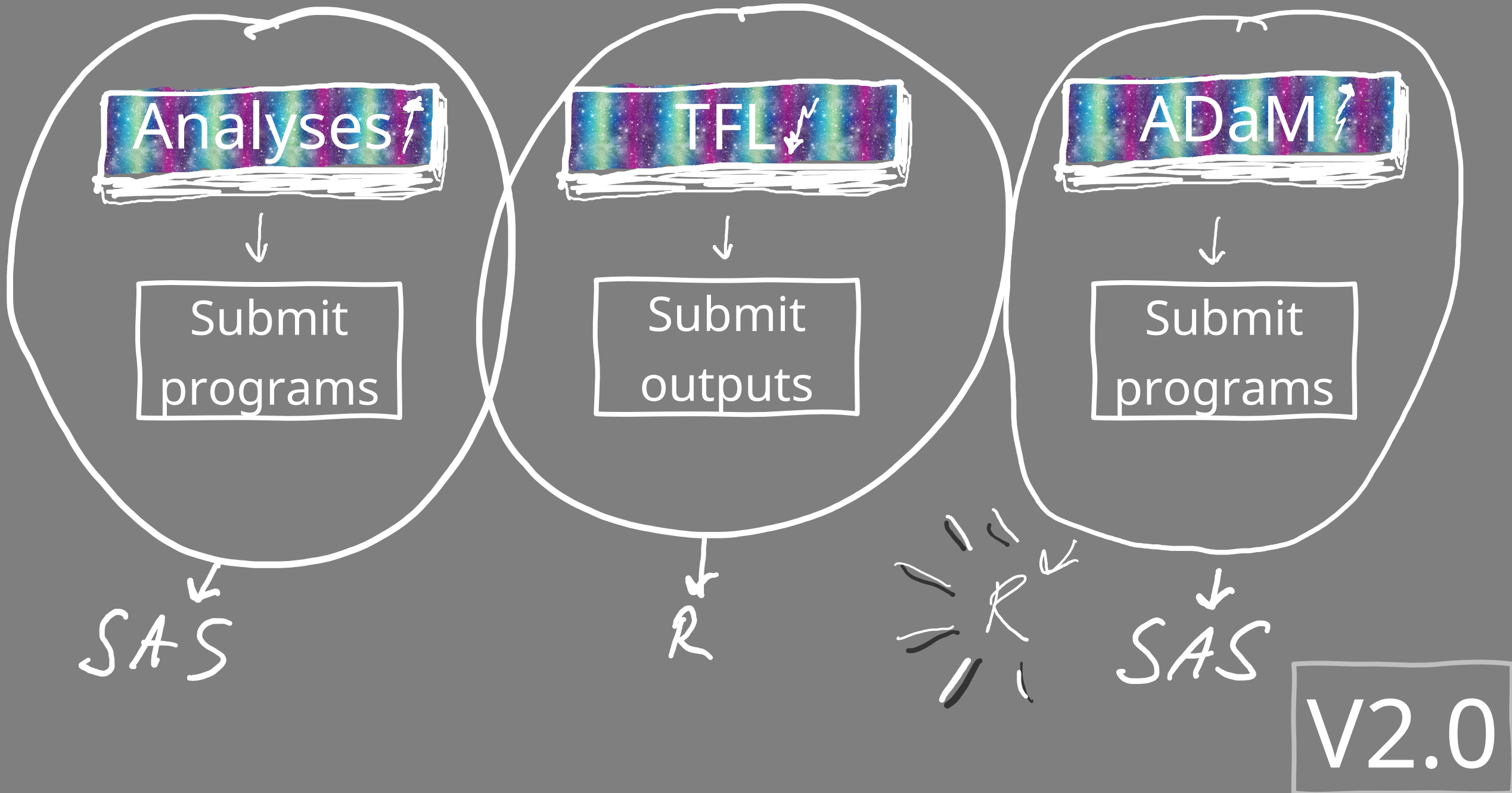
R



Package

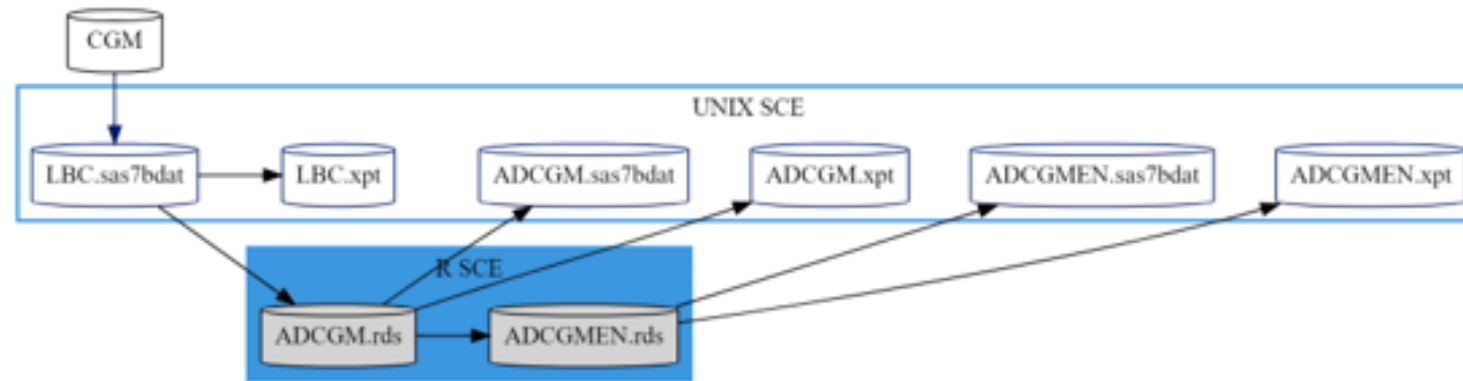


ADRG



Novo Nordisk plans to create the CGM ADaM datasets using the programming language R to substantially reduce the processing time. In addition to the SAS software programs submitted as part of the eCTD submission for the BLA under module 5.3.5.1 for each trial, Novo Nordisk plans to submit the R programs creating all CGM related ADaM datasets. The software specifications of R and any publicly available R package used in the R programs will be specified in the ADRG. Any Novo Nordisk developed packages which are not publicly available will be submitted as part of the eCTD submission for the BLA under module 5.3.5.1 for each trial.

The specifications of any Novo Nordisk developed or publicly available R packages used in the generation of ADaM datasets will be specified in the ADRG. Any Novo Nordisk developed package which is not publicly available will be submitted as part of the eCTD submission under Module 5.3.5.1 with instructions in the ADRG on how to unpack and install from an associated .txt file using the publicly available R package "pkglite".

Figure 1 CGM Data processing flow for phase 3 trials

SCE: statistical computing environment

The SDTM.LBC domain is generated from the raw CGM data delivered by external vendor. The ADaM.ADCGM and ADaM.ADCGMEN are derived from the LBC.sas7bdat domain in an R statistical computing environment. From the R object files (.rds) the .sas7bdat and .xpt versions of ADCGM and ADCGMEN are rendered.



Not
Submitted



→ ADRG

Language	SAS	R
Platform	HP-UX HP IPF B.11.31 U ia64	Red Hat Enterprise Linux 8.6 (Ootpa) x86_64, linux-gnu
Software	SAS v9.4 (TS1M5)	R version 4.0.4 (2021-02-15)
Date of reference (Software specific)	1 January 1960	1 January 1970

8 Appendix: Instruction to ADaM Programs in R

8.1 Install R

Download and install R 4.0.4 for Windows from

<https://cran.r-project.org/bin/windows/base/old/4.0.4/R-4.0.4-win.exe>.

8.2 Specify R package repository

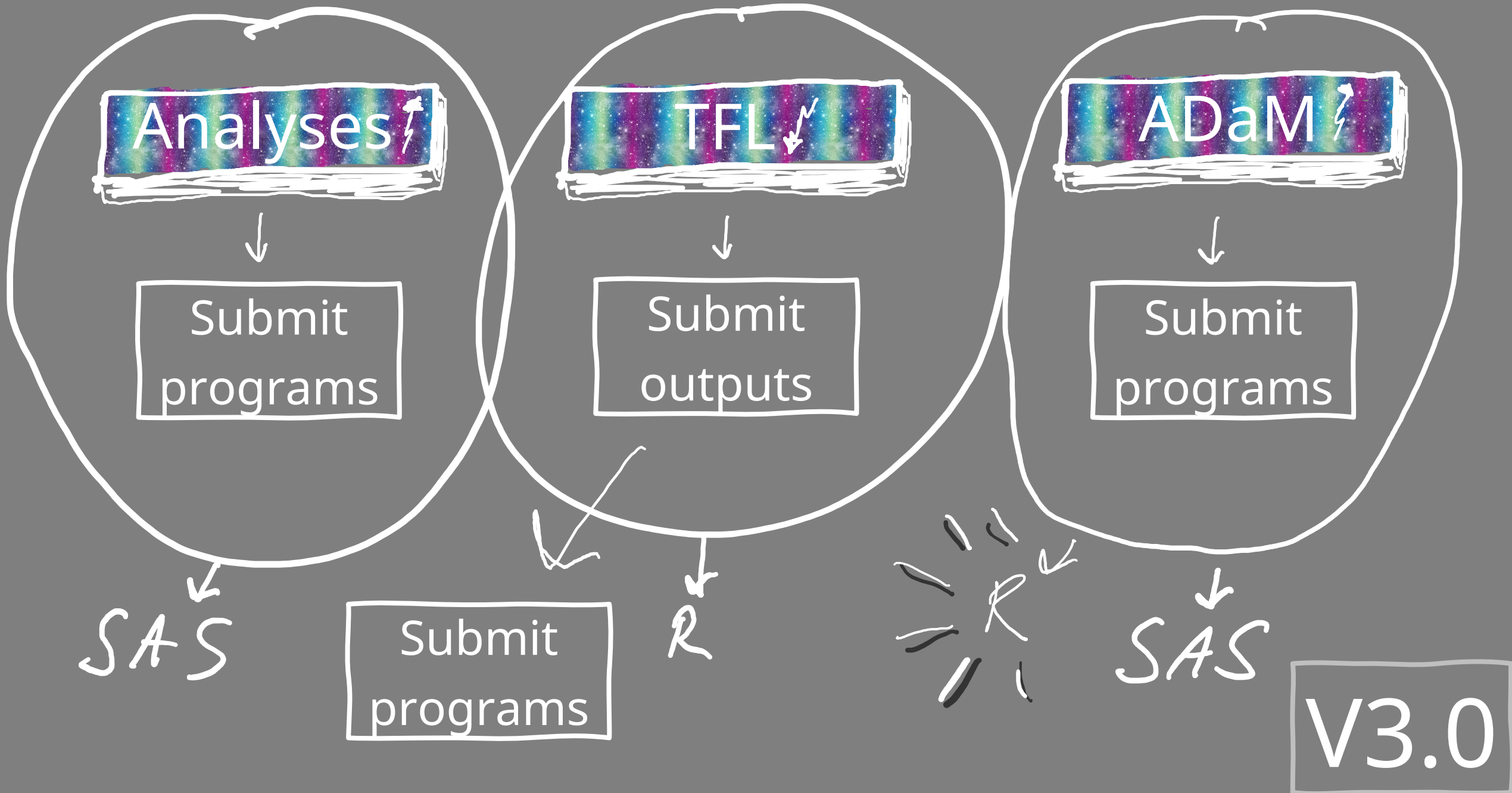
The R packages are based on CRAN at 2021-02-15. To install the exact R package versions used in this project, run the code below to set the snapshot repository.

```
options(repos = "https://cran.microsoft.com/snapshot/2021-02-15/")
```

8.3 Install open-source R packages

In the same R session, install the required packages by running the code below.

```
install.packages(c("dtplyr", "lubridate"))
```



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 **thomas-neitmann** Add proposal for pilot 3  20f1f21 16 days ago  70 commits

 .devcontainer	Add minutes for March & April meetings (#79)	6 months ago
 Documents	Add proposal for pilot 3	16 days ago
 Minutes	JBR: Minutes of 10-07-22 meeting	16 days ago
 R	add recent batch of minutes (#71)	8 months ago
 docs	Add minutes for March & April meetings (#79)	6 months ago
 prototyping	Add source for distill web site (#48)	12 months ago
 renv	Add source for distill web site (#48)	12 months ago
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 .gitignore	Add source for distill web site (#48)	12 months ago