

Flavors of the Pharmaverse

WiFi: Posit Conf 2024
Password: conf2024



Information

- There are gender-neutral bathrooms located on levels 3,4,5,6 &7
- The meditation/prayer room is located in 503
 - Available Monday & Tuesday 7a.m. - 7p.m., Wednesday 7a.m. - 5p.m.
- The lactation room is located in located in 509
 - Available Monday & Tuesday 7a.m. - 7p.m., Wednesday 7a.m. - 5p.m.


Conduct

- Participants who do not wish to be photographed have red lanyards; please note everyone's lanyard colors before taking a photo and respect their choices.
- The Code of Conduct and COVID policies can be found at:
<https://posit.co/code-of-conduct/>.
 - Please review them carefully.
 - You can report Code of Conduct violations in person, by email, or by phone. Please see the policy linked above for contact information.

What to expect from this workshop

- Learn about what the Pharmaverse is
- R packages to support Clinical Reporting in R
 - Create ADaM datasets from SDTM
 - Multiple ways to create tables
 - Learn about ARD's
- Hands-on Exercises & Discussions

Workshop Expectations

- What to do if you find a  ?
- Ask questions!
- Be respectful to each other and yourself

Workshop Instructors

- Who are we?
- What do we do?
- Why are we here?

Becca Krouse



Daniel Sjoberg



Andrew Bates



Ellis Hughes



Casey Aguilar-Gervase

Who are you?!

Meet the people around you!



Who are you?! Now we want to meet you!

R Experience?

- Never used R?
- 2 years
- 5 years
- Used Tidyverse?
- Used Pharmaverse Packages?

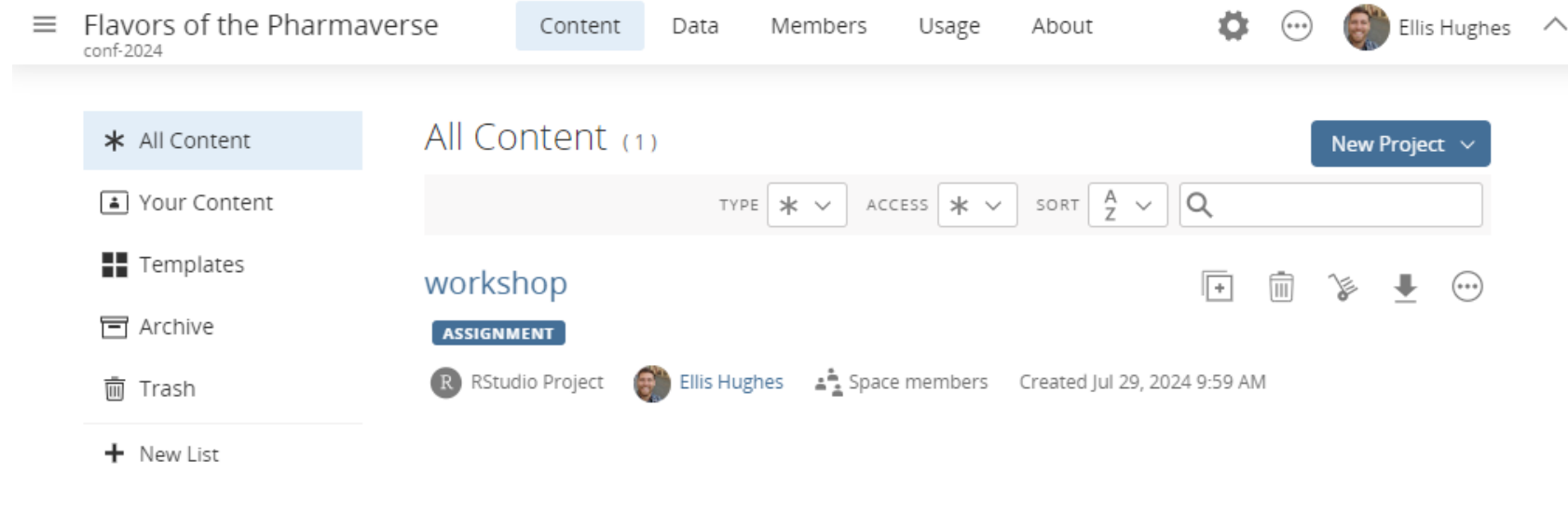
Pharma Experience

- CDISC
- TLF Generation
- validation

Our environment: **posit**™ Cloud



- For consistency, we'll be working in [Posit Cloud](https://bit.ly/posit_2024_Pharmaverse) (https://bit.ly/posit_2024_Pharmaverse)
- We've installed and configured everything for you



- Following the course, all content from this workshop will be available on GitHub (<https://github.com/posit-conf-2024/pharmaverse>)

Posit Cloud

posit.cloud/spaces/521669/content/8480560

Flavors Of The Pharmaverse / workshop

RAM ⚙️ 👤 Ellis Hughes

File Edit Code View Plots Session Build Debug Profile Tools Help

Go to file/function Addins

Untitled1*

Run ↗️ ⬆️ ⬇️ Source

```
1 ## This is the edit window/source pane.
2
3 print("Your R Code Gets Written and Saved Here!")
```

3:48 (Top Level) R Script

Environment History Connections Tutorial

Import Dataset 1.72 MiB

Global Environment

Environment is empty

Files Plots Packages Help Viewer Presentation

New Folder New Blank File Upload Delete Rename More

Cloud > project

	Name	Size	Modified
📁	..		
📄	.Rhistory	0 B	Jul 29, 2024, 9:59 AM
📄	project.Rproj	205 B	Jul 31, 2024, 1:49 PM

Console Terminal Background Jobs

R 4.4.1 . /cloud/project/

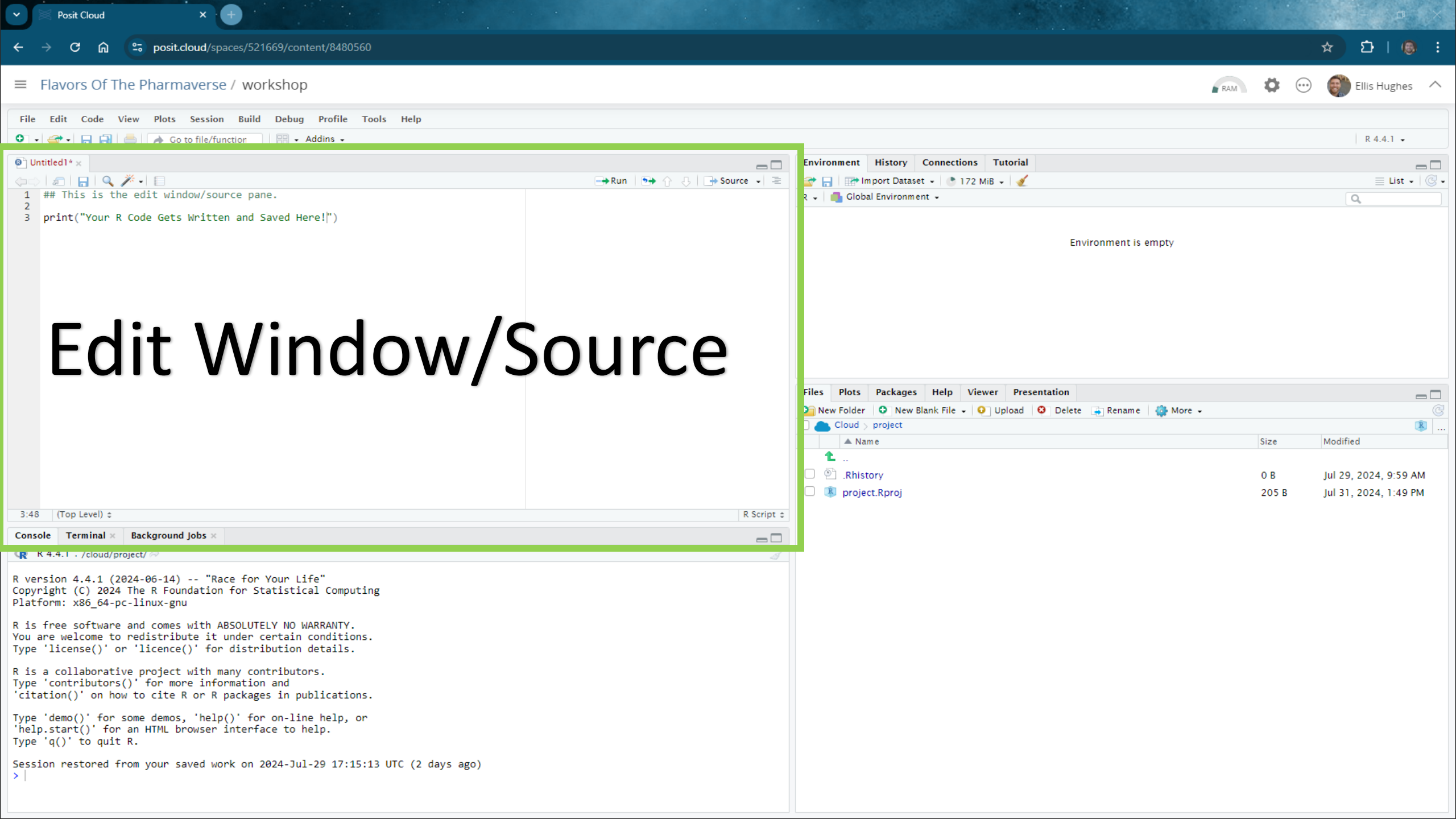
R version 4.4.1 (2024-06-14) -- "Race for Your Life"
Copyright (C) 2024 The R Foundation for Statistical Computing
Platform: x86_64-pc-linux-gnu

R is free software and comes with ABSOLUTELY NO WARRANTY.
You are welcome to redistribute it under certain conditions.
Type 'license()' or 'licence()' for distribution details.

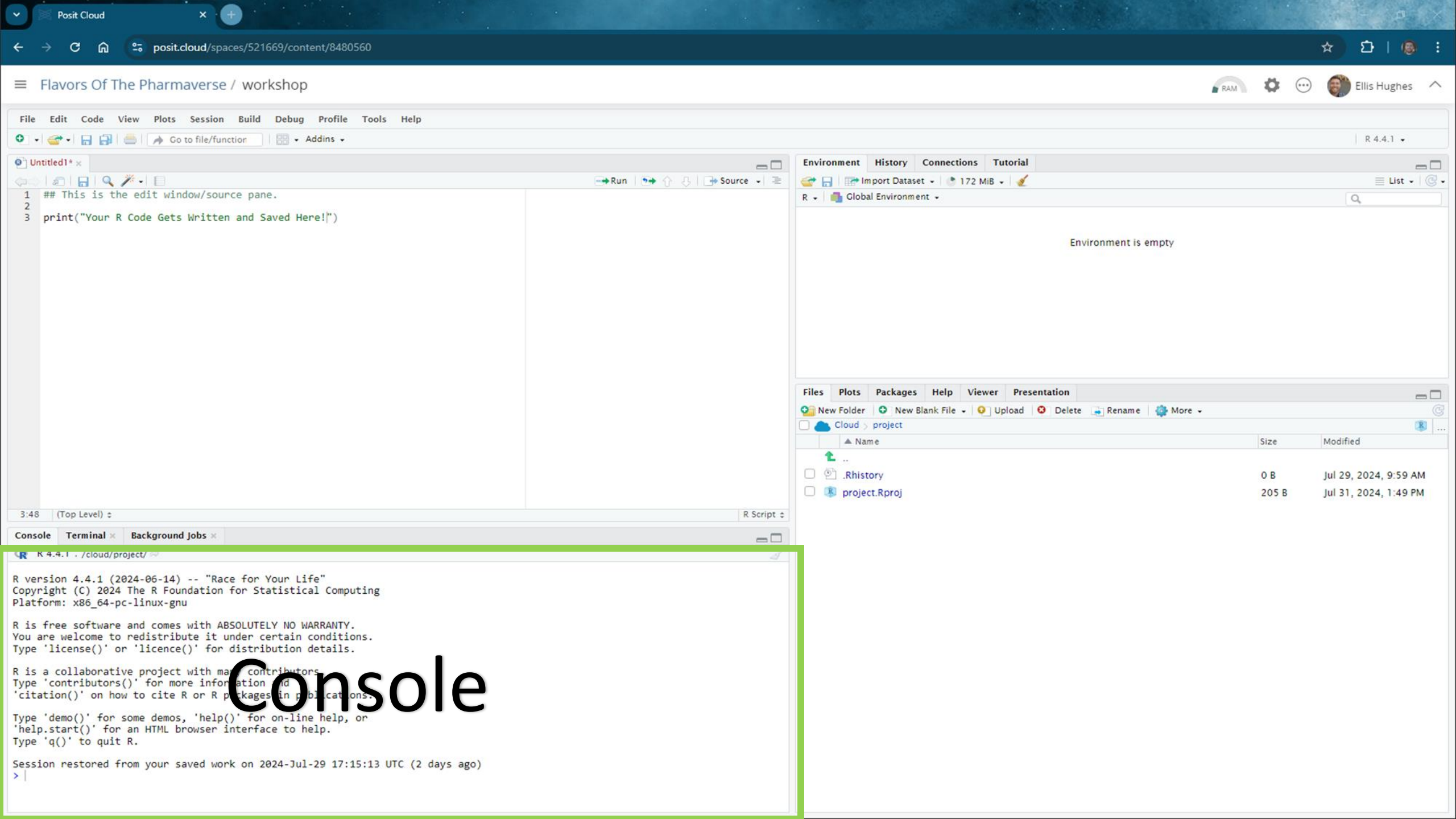
R is a collaborative project with many contributors.
Type 'contributors()' for more information and
'citation()' on how to cite R or R packages in publications.

Type 'demo()' for some demos, 'help()' for on-line help, or
'help.start()' for an HTML browser interface to help.
Type 'q()' to quit R.

Session restored from your saved work on 2024-Jul-29 17:15:13 UTC (2 days ago)
> |



Edit Window/Source



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Console

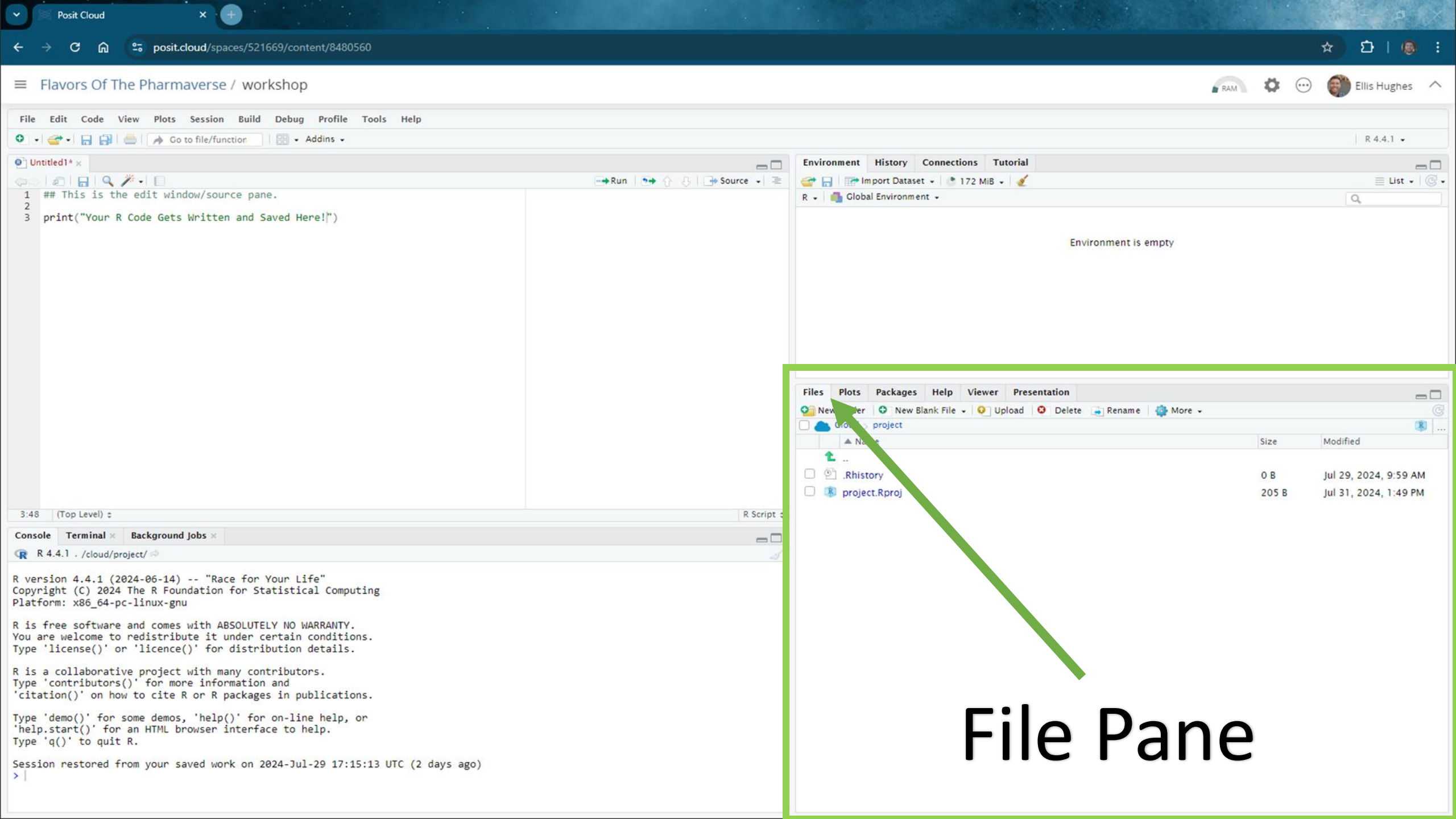
Environment History Connections Tutorial

Import Dataset 172 MiB

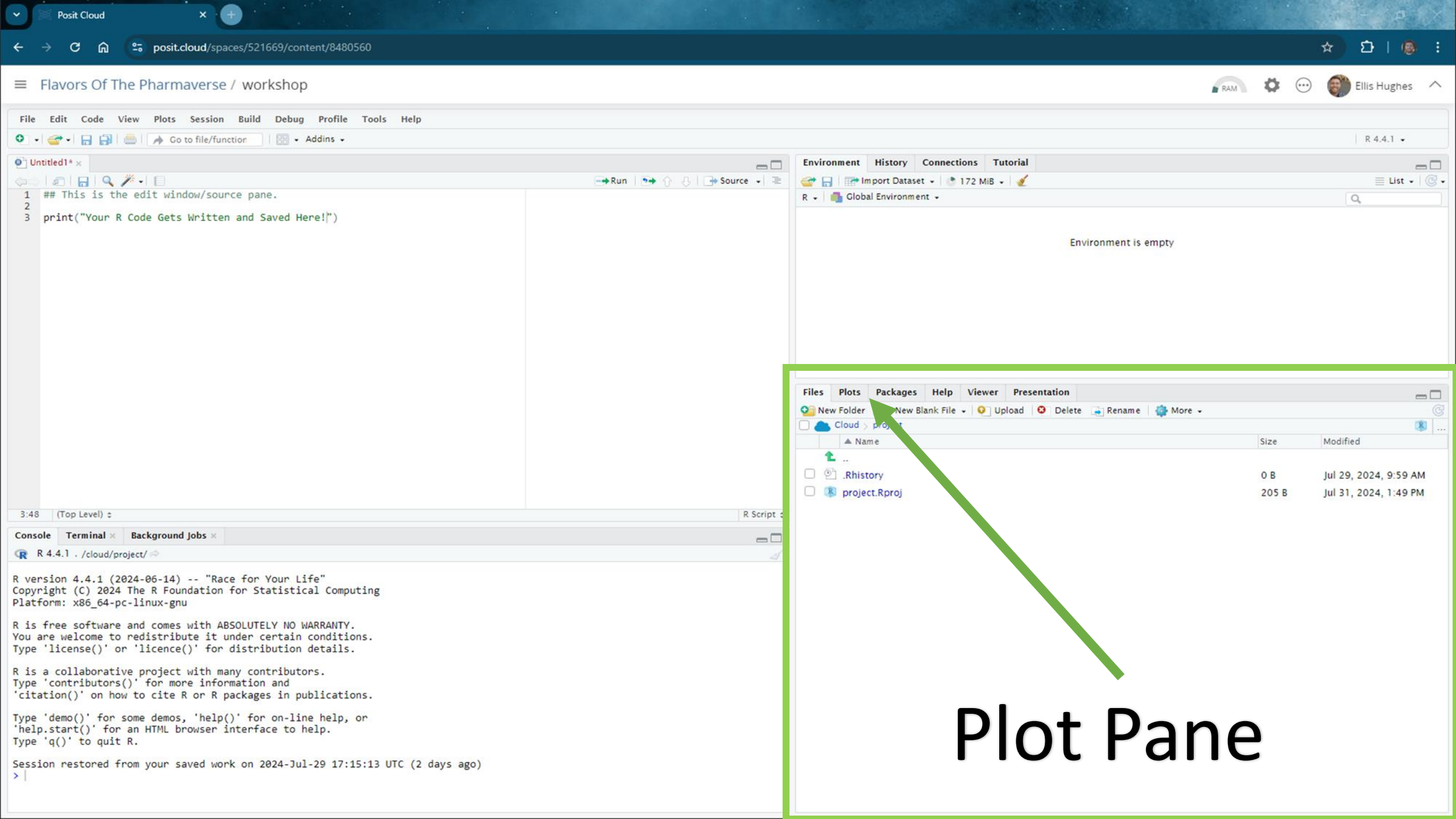
R Global Environment

Environment is empty

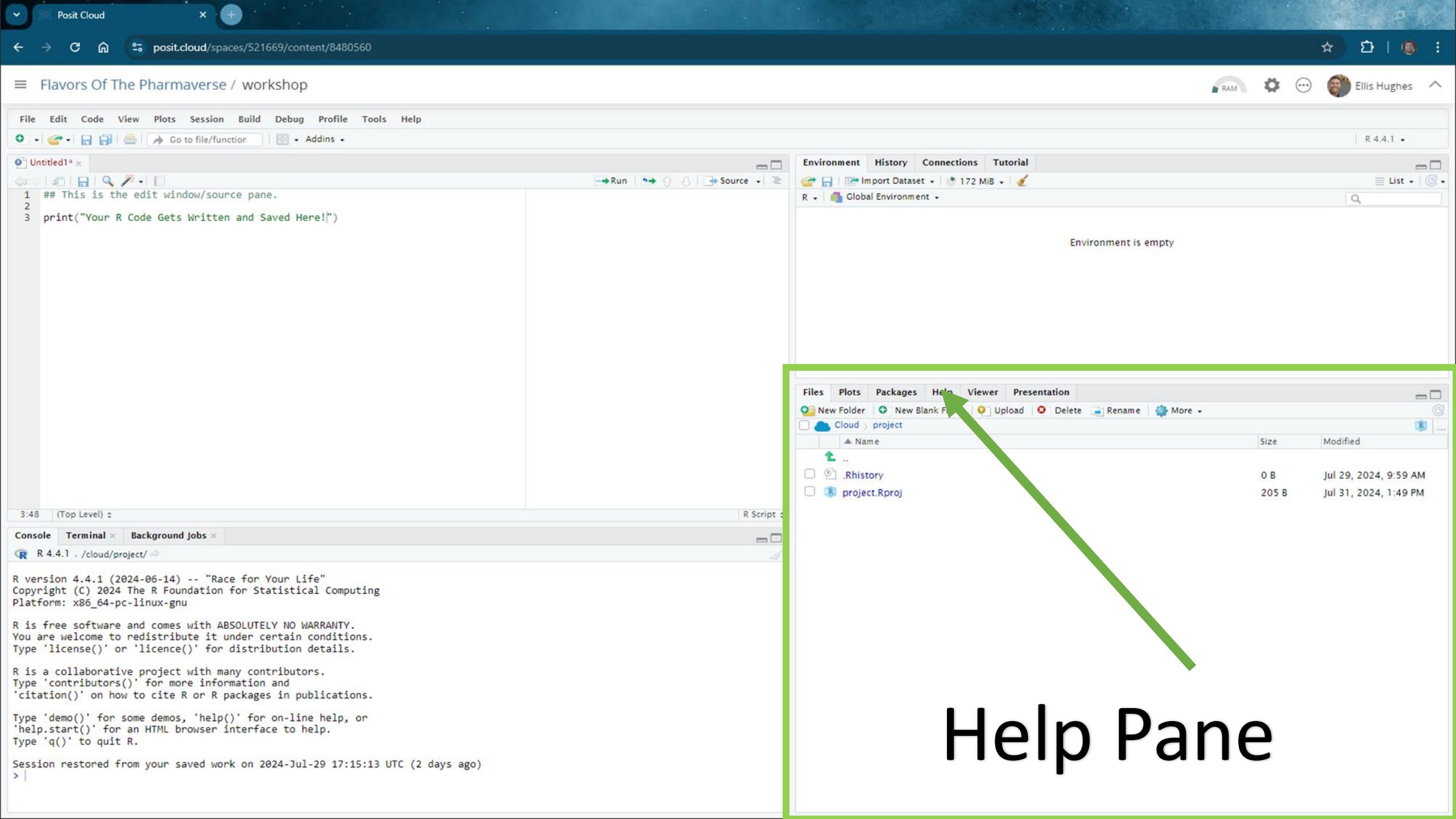
Files Plots Packages Help Viewer Presentation		
New Folder New Blank File Upload Delete Rename More		
Cloud > project		
	Name	Size Modified
	..	
	.Rhistory	0 B Jul 29, 2024, 9:59 AM
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File Pane



Plot Pane



Help Pane

Posit Cloud

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Environment History Connections Tutorial

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Environment

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Cloud > project

	Name	Size	Modified
	..		
	.Rhistory	0 B	Jul 29, 2024, 9:59 AM
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Time	Activity
09:00 – 09:20	Introduction & Welcome to the Pharmaverse
09:20 - 10:30	Session 1 – ADaM
10:30 - 11:00	Coffee break
11:00 - 12:30	Session 2 – Tables & ARD Intro
12:30 - 13:30	Lunch break
13:30 - 15:00	Session 3 – ARD Based Tables
15:00 - 15:30	Coffee break
15:30 - 17:00	Session 4 – Recap and Discussion



(Welcome To The Jungle starts playing somewhere off in the distance...)

Welcome to the Pharmaverse

Pharmaverse

- <https://pharmaverse.org/>

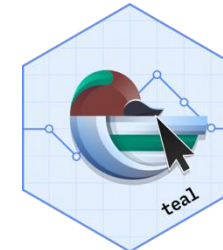
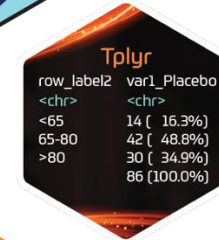
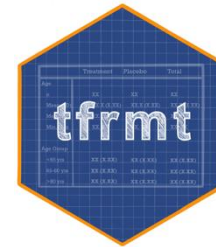
- Goals

- Align pharma industry on a set of open source packages based in R to deliver the clinical data pipeline
- Design, collaborate, and deliver new solutions where suitable tools do not exist (ie admiral)



E2E Clinical Reporting Packages

- <https://pharmaverse.org/e2eclinical/>



Not to give anyone ideas, but it is not a “verse” like tidyverse

```
> library(pharmaverse)
Error in library(pharmaverse) : there is no package called 'pharmaverse'
> |
```

Industry working on a similar goal

- Standards (ie CDISC) means standard tools can be created and shared
- Collaboration in the “post competitive” space means everyone has access to free solutions
- Team and Regulators seeing consistent packages being used across multiple teams speeds up development and review

TRUE or FALSE?

Pharmaverse makes decisions on how R should be used in the pharma space	FALSE
Pharmaverse serves as a source of information on available R packages that help with the Clinical Data Workflow	TRUE
Pharmaverse allows commercial interests from Collaborators to drive decisions	FALSE
The scope of Pharmaverse starts at STDm and ends at TLF creation	FALSE
Pharmaverse does not require you to be part of it use the tools coming from it	TRUE
Pharmaverse packages need to be reviewed by your own GXP process	TRUE

Resources

- Website:
 - Pharmaverse.org
- R packages and github
 - <https://github.com/pharmaverse/>
- Youtube Channel
 - <https://www.youtube.com/channel/UCxQFEv8HNqM01DXzdQLCy6Q>
- Blog
 - <https://pharmaverse.github.io/blog/>
- Community
 - pharmaverse.slack.com

Lets get started into the Pharmaverse!





Data Collection
CDASH



Data Aggregation
SDTM



Analysis
ADaM



Results
???



Figure 10-10: Management of a patient with a suspected diagnosis of aortic dissection

The flowchart outlines the following pathways:

- Initial Presentation:**
 - Typical symptoms:** Sudden onset of severe chest pain, tearing or ripping in character, radiating to the back.
 - Physical findings:**
 - Normal vital signs.
 - Normal physical exam.
 - Abnormal physical exam: Hypertension, tachycardia, bradycardia, hypotension, diaphoresis, unequal arm blood pressures, new murmur, neurological deficits.
- Diagnostic Pathways:**
 - Typical symptoms + Normal vital signs/physical exam:**
 - Chest X-ray: Normal → ECG → Normal → Dismissed.
 - Chest X-ray: Abnormal → CT/MRI → Dismissed.
 - Typical symptoms + Abnormal physical exam:**
 - ECG: Normal → CT/MRI → Dismissed.
 - ECG: Abnormal → Dismissed.
 - Atypical symptoms + Normal vital signs/physical exam:**
 - ECG: Normal → Dismissed.
 - ECG: Abnormal → Dismissed.
 - Atypical symptoms + Abnormal physical exam:**
 - ECG: Normal → Dismissed.
 - ECG: Abnormal → Dismissed.
- Management Pathways:**
 - Diagnosed Aortic Dissection:**
 - Type A:** Surgical management (Open repair or Endovascular repair).
 - Type B:** Medical management (Beta-blockers, pain control).
 - Aortic Aneurysm:**
 - Ascending aortic aneurysm:** Surgical management (Open repair or Endovascular repair).
 - Descending aortic aneurysm:** Endovascular repair.

Data Collection

Km	STATION	DIVISION	INSTRUMENT	CHECKED	EXTENSION	COMMENTS	DATE OF SURVEY	REMARKS	STATUS
1	0+00	0+00	0+00	0+00	0+00	0+00	0+00	0+00	0+00
2	0+00	0+00	0+00	0+00	0+00	0+00	0+00	0+00	0+00
3	0+00	0+00	0+00	0+00	0+00	0+00	0+00	0+00	0+00
4	0+00	0+00	0+00	0+00	0+00	0+00	0+00	0+00	0+00
5	0+00	0+00	0+00	0+00	0+00	0+00	0+00	0+00	0+00
6	0+00	0+00	0+00	0+00	0+00	0+00	0+00	0+00	0+00
7	0+00	0+00	0+00	0+00	0+00	0+00	0+00	0+00	0+00
8	0+00	0+00	0+00	0+00	0+00	0+00	0+00	0+00	0+00

Km	STATION	DATE	REMARKS
1	0+00	0+00	0+00
2	0+00	0+00	0+00
3	0+00	0+00	0+00
4	0+00	0+00	0+00
5	0+00	0+00	0+00
6	0+00	0+00	0+00
7	0+00	0+00	0+00
8	0+00	0+00	0+00

Data Aggregation

[illegible]

Results



Seq	Variable	Value	Source
1	Seq	00000	00000
2	Seq	00000	00000
3	Seq	00000	00000
4	Seq	00000	00000
5	Seq	00000	00000
6	Seq	00000	00000
7	Seq	00000	00000
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9	Seq	00000	00000
10	Seq	00000	00000
11	Seq	00000	00000
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100	Seq	00000	00000



Outcome	SP	Group A		Group B	
		95% CI	95% CI	95% CI	95% CI
	Mean (SD)	9.40 (9.400)	9.40 (9.400)		
Group A	SD	9.40	9.40		
Group B	SD			9.40 (9.400)	9.40 (9.400)
Adjusted change from baseline Mean (SD)		9.40 (9.400)	9.40 (9.400)	9.40 (9.400)	9.40 (9.400)
95% confidence interval for adjusted mean difference vs. Group A (SD)		9.40, 9.40	9.40, 9.40	9.40, 9.40	9.40, 9.40
95% confidence interval for difference between vs. Group B (SD)				9.40, 9.40	9.40, 9.40
95% confidence interval for difference between vs. Group B (SD)				9.40, 9.40	9.40, 9.40
Outcome	SP	Group A		Group B	
		95% CI	95% CI	95% CI	95% CI
	Mean (SD)	9.40 (9.400)	9.40 (9.400)		
Group A	SD	9.40	9.40		
Group B	SD			9.40 (9.400)	9.40 (9.400)
Adjusted change from baseline Mean (SD)		9.40 (9.400)	9.40 (9.400)	9.40 (9.400)	9.40 (9.400)
95% confidence interval for adjusted mean difference vs. Group A (SD)		9.40, 9.40	9.40, 9.40	9.40, 9.40	9.40, 9.40
95% confidence interval for difference between vs. Group B (SD)				9.40, 9.40	9.40, 9.40
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Data Collection

Data Aggregation

Results