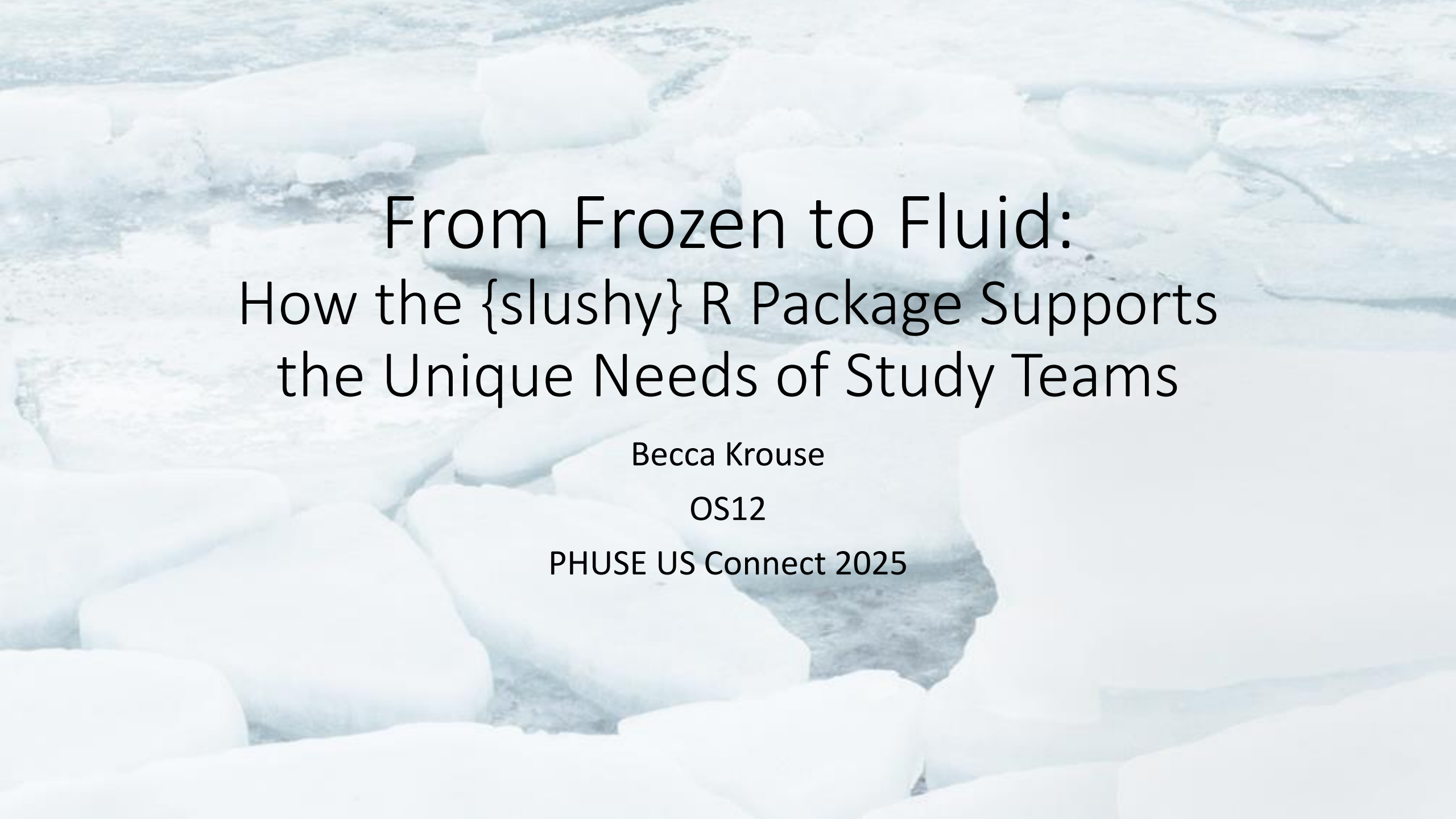




From Frozen to Fluid: How the {slushy} R Package Supports the Unique Needs of Study Teams

Becca Krouse

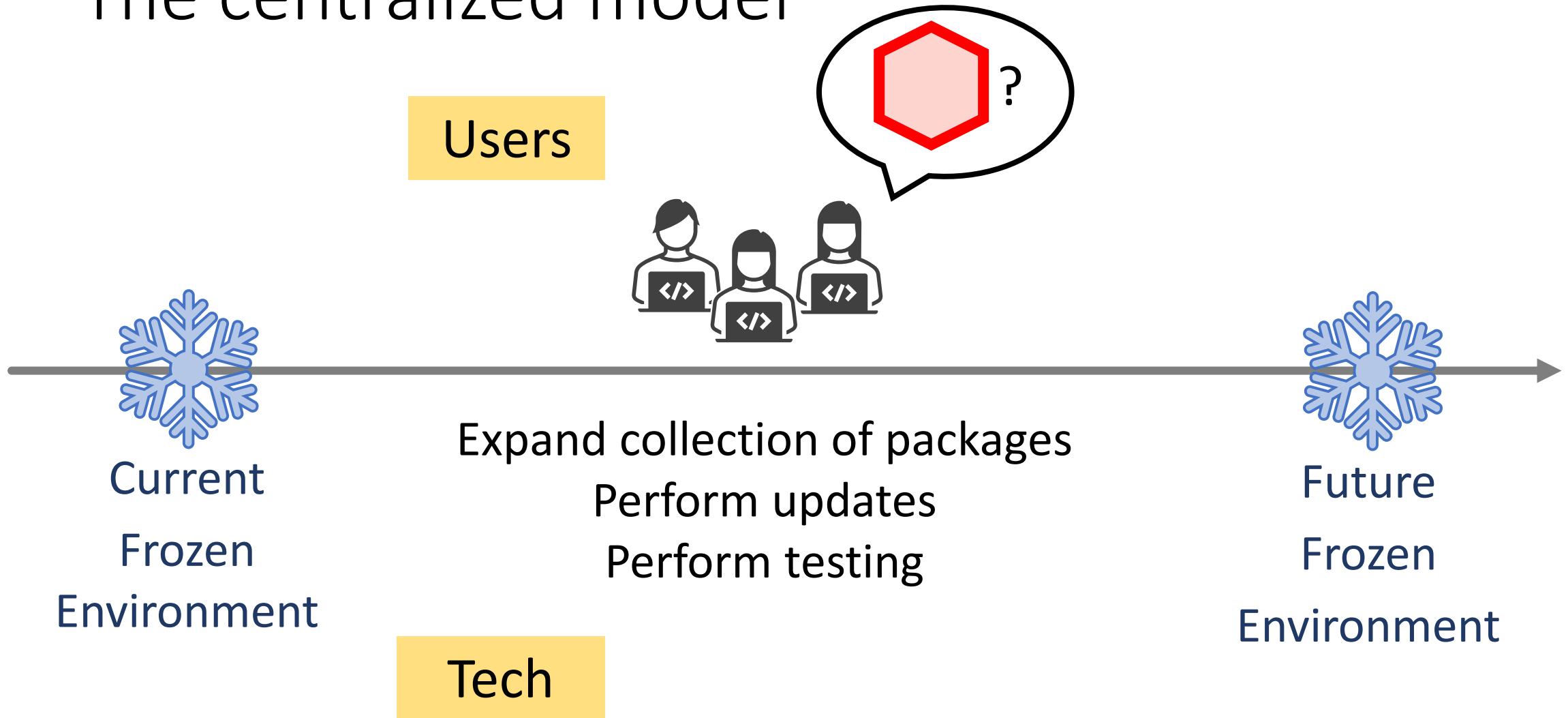
OS12

PHUSE US Connect 2025

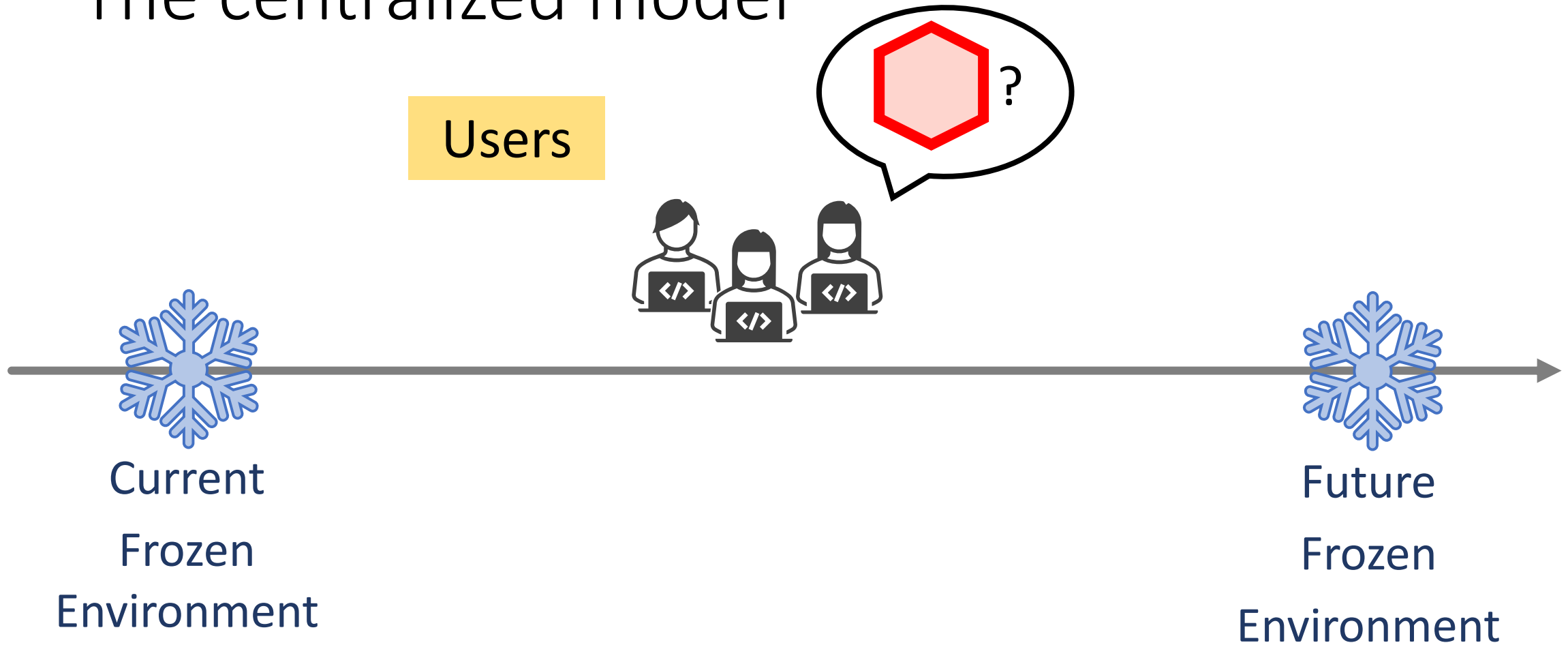
Disclaimer

This presentation is my personal opinion
and not that of my organization.

The centralized model

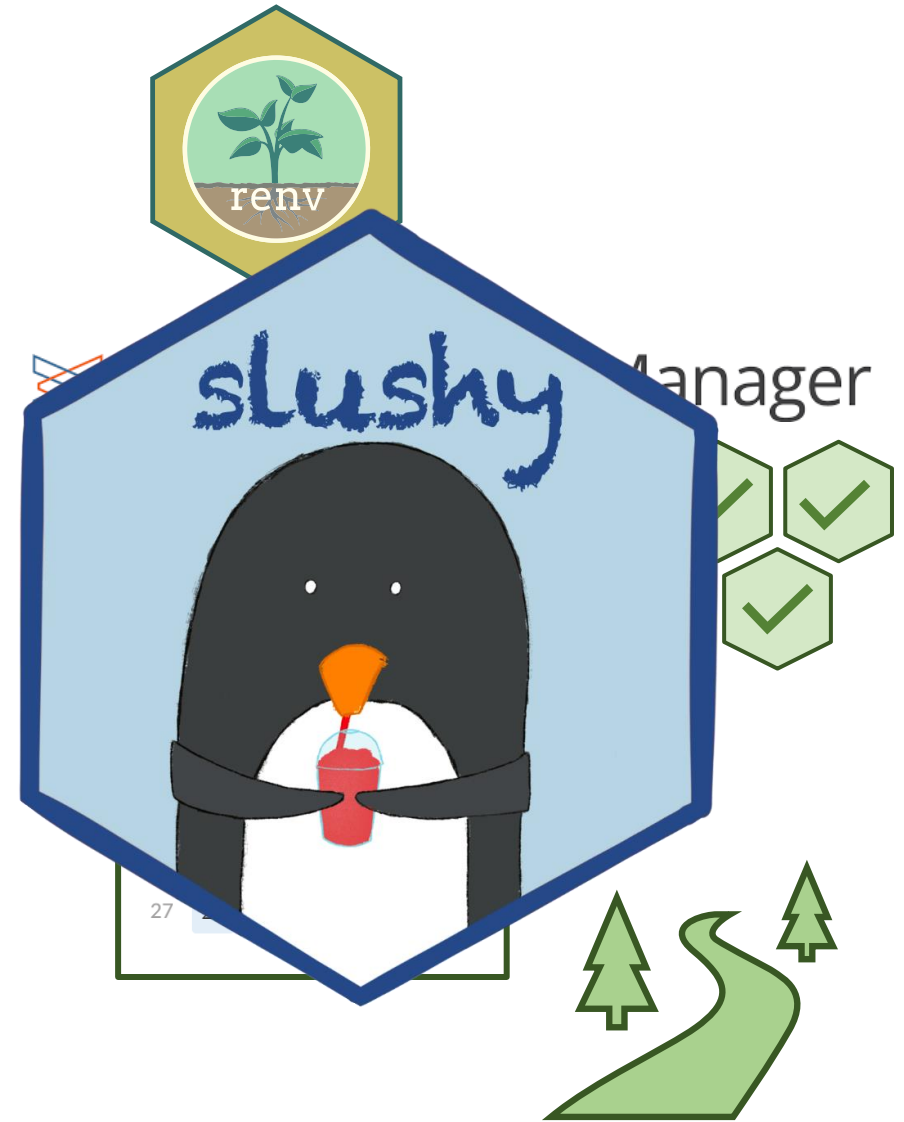
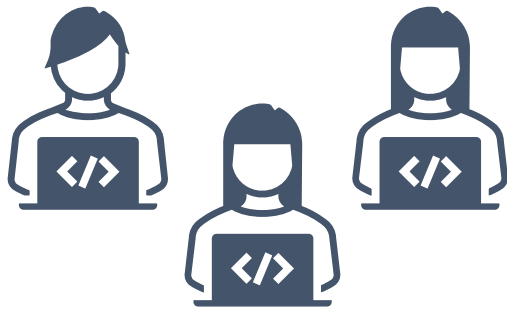


The centralized model

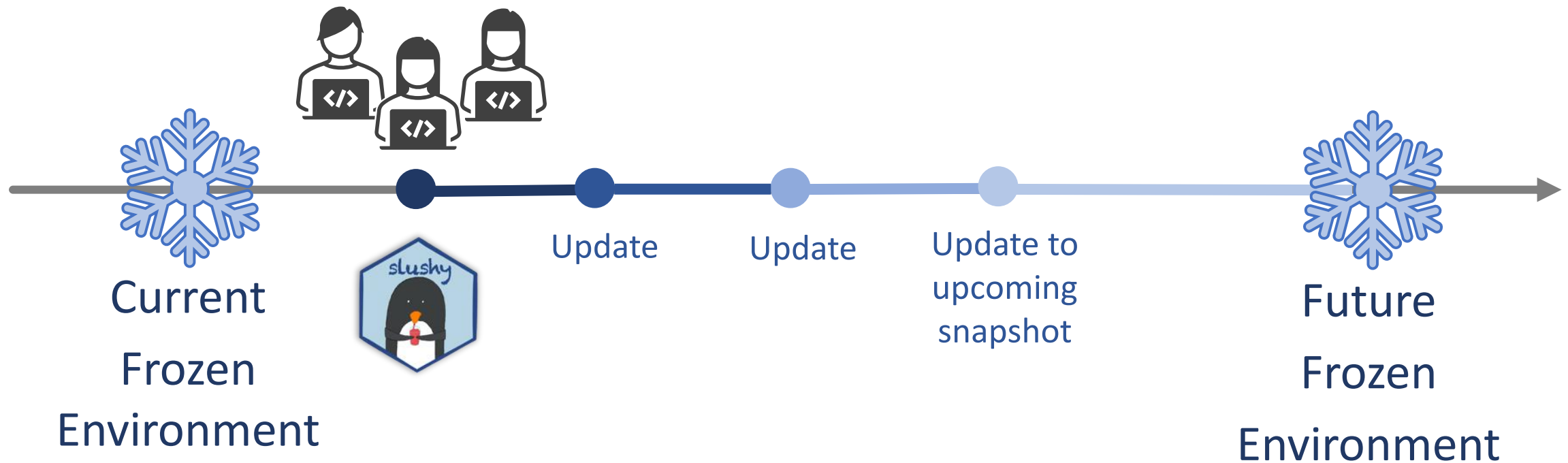


Needs in the meantime

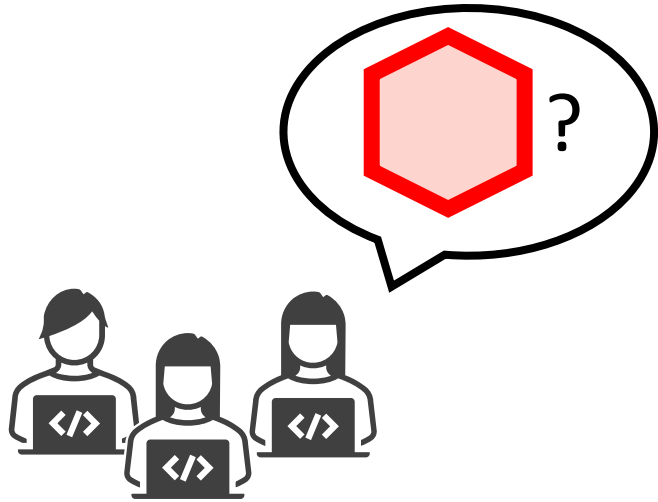
- ✓ Reproducible code
- ✓ Access to necessary packages
- ✓ Smooth transition to future frozen environment
- ✓ Extra supports to ease burden, stay on track, and make everything “just work”



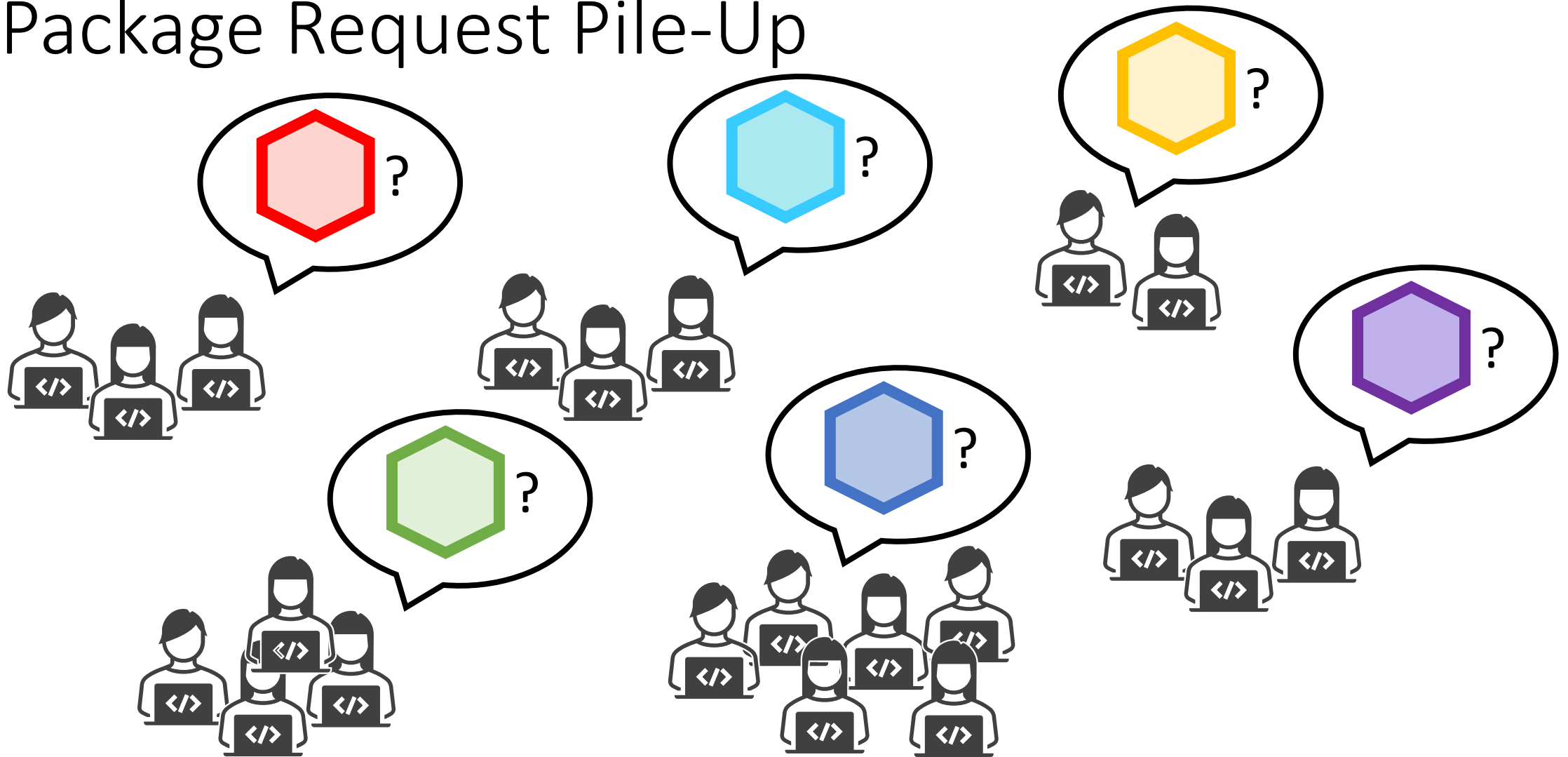
{slushy} as a bridge to the future



Package Request Pile-Up



Package Request Pile-Up



The waiting game



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We are evolving

A Risk-based Approach for Assessing R package Accuracy within a Validated Infrastructure



R Submissions Working Group Home Meeting Minutes How to Join Pilots ▾ Site Development

A Risk-based Approach for Assessing R package Accuracy within a Validated Infrastructure

Andy Nicholls, Statistics Director, Head of Statistical Data Sciences, GSK

Paulo R. Bargo, Director Scientific Computing, Statistics & Decision Sciences, Janssen R&D

John Sims, Director, Analytical Systems Architect & Data Science - Pfizer Vaccine Research

On behalf of the R Validation Hub, an R Consortium-funded ISC Working Group

Background

Pilot principles:

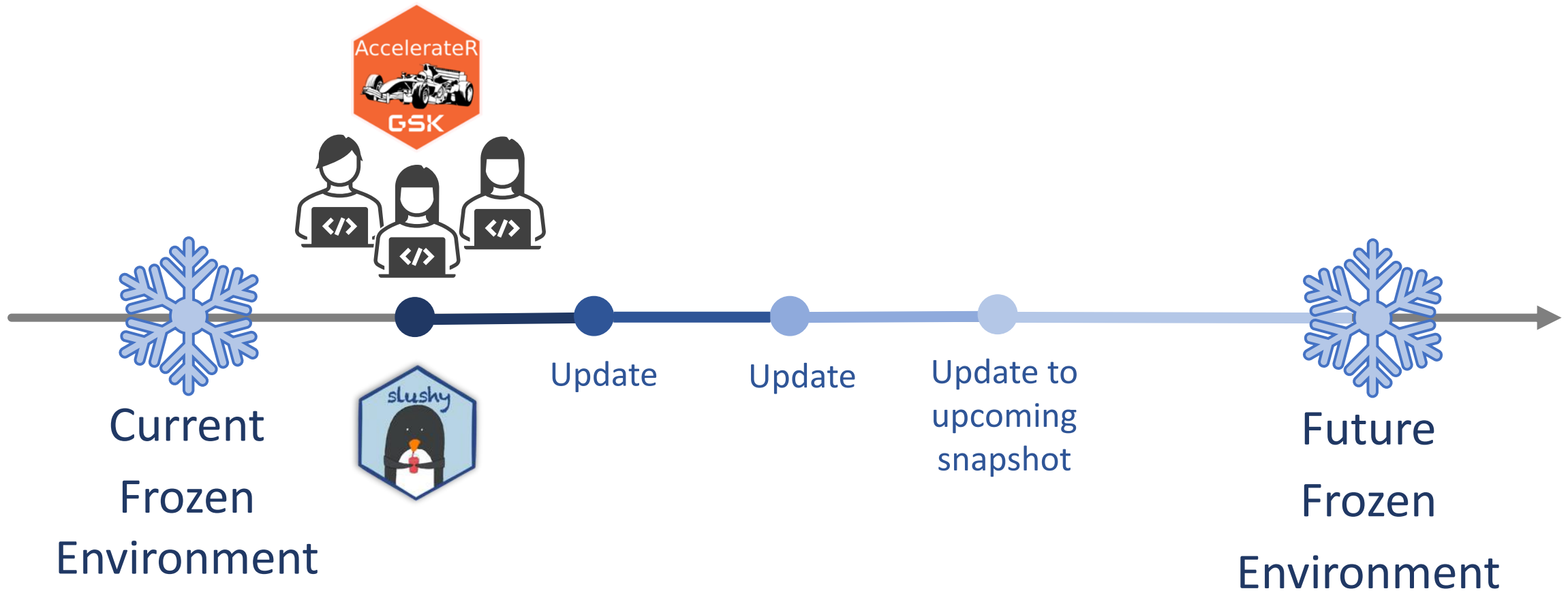
Provide open examples of submitting R-based clinical trial data/analysis packages to FDA.

- All pilots will be submitted from R consortium (non-profit identity) to FDA. Simulated data will be used.
- All data, codes and documents will be fully available to public.
- FDA Staff will be engaged to reproduce analysis results.
- Submitter and FDA Staff will provide feedback on current process/system
- Contributions from multiple companies/organizations are preferred. Avoid bias to any company/organization specific tools.

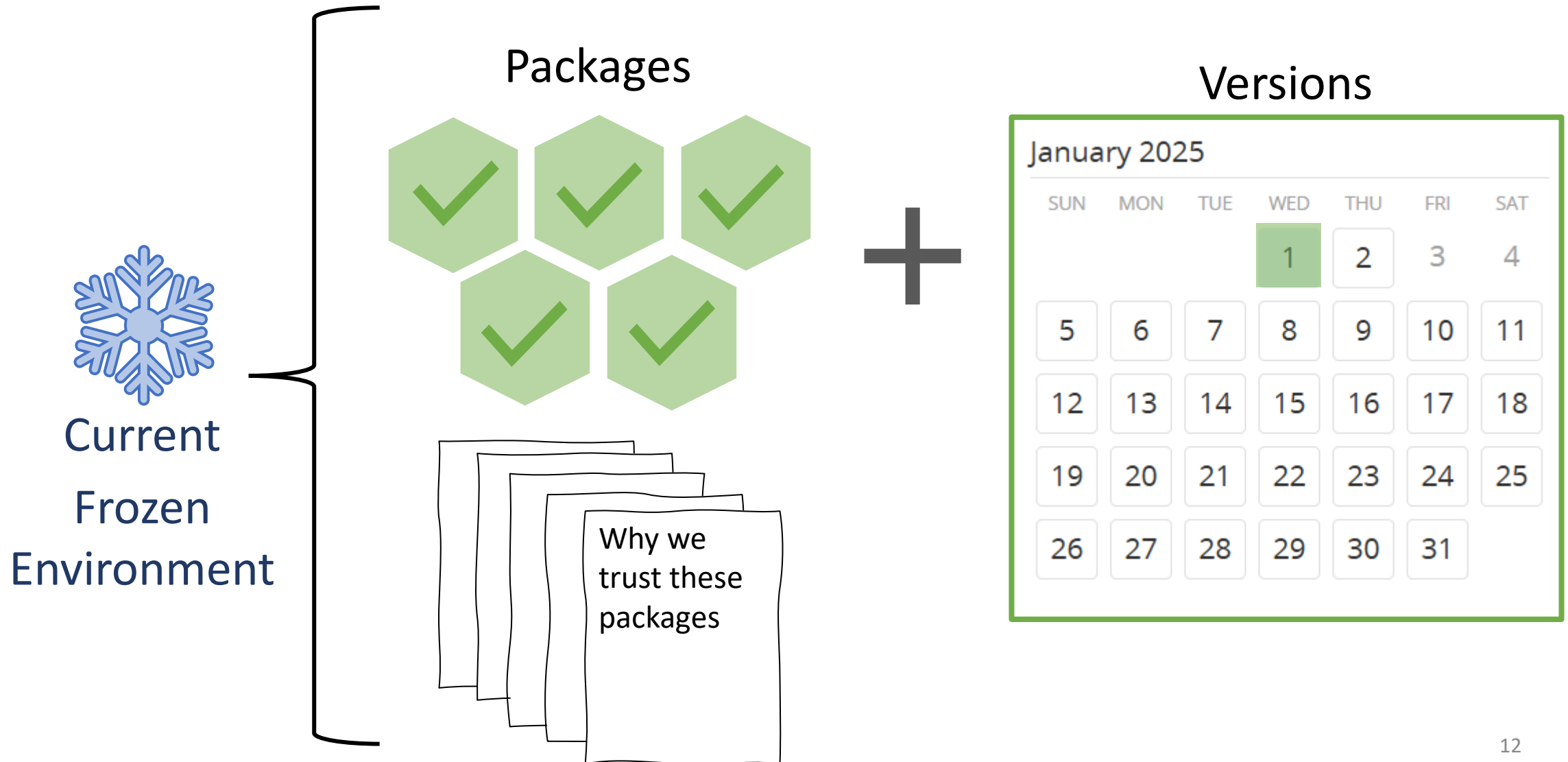
You can view more details about each of the current pilots by visiting their dedicated pages below:

- [Pilot 1](#): Common analyses
- [Pilot 2](#): Shiny application submission
- [Pilot 3](#): ADaM datasets
- [Pilot 4](#): Alternative formats

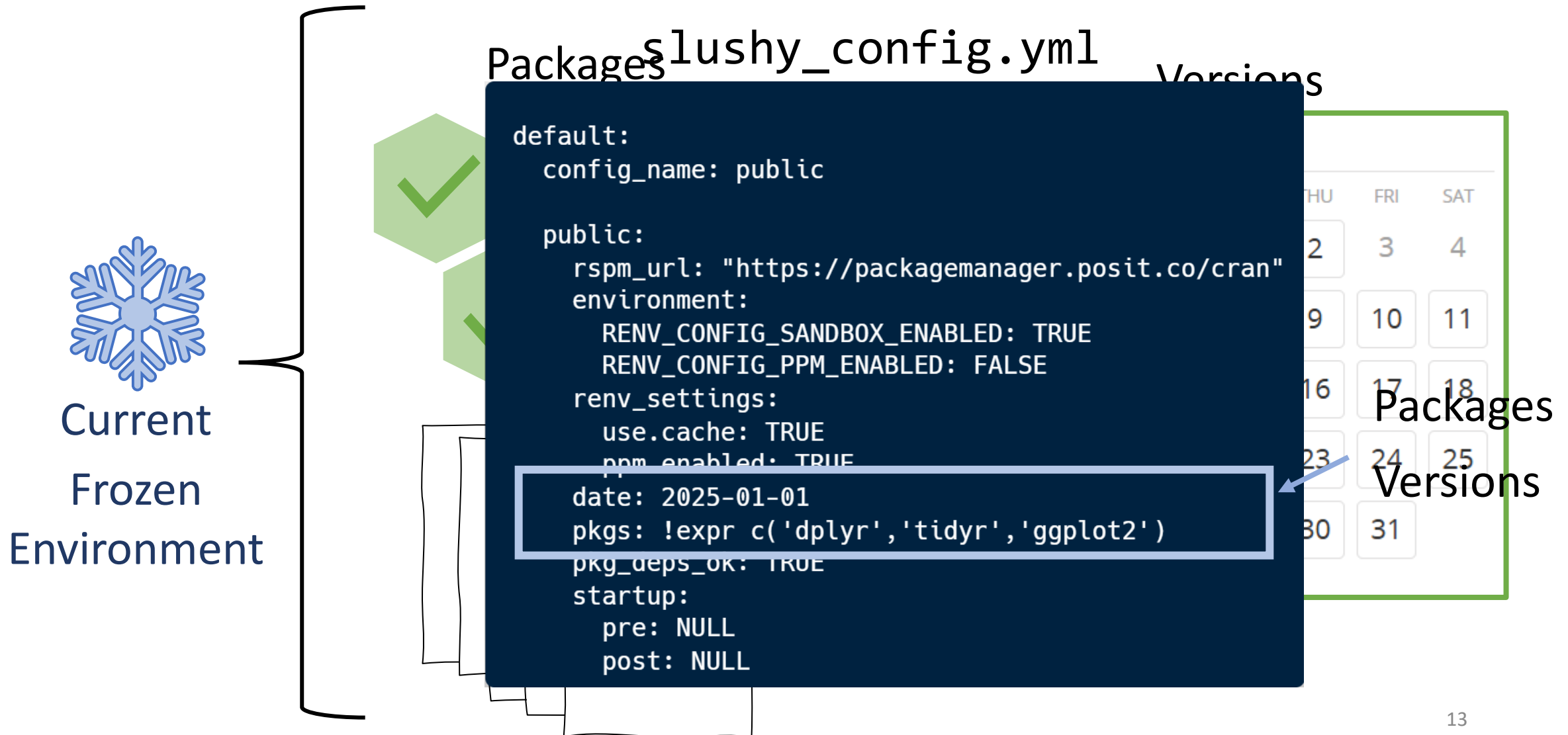
{slushy} as a pathway to the future



Start By Aligning With Central Team



Start By Aligning With Central Team



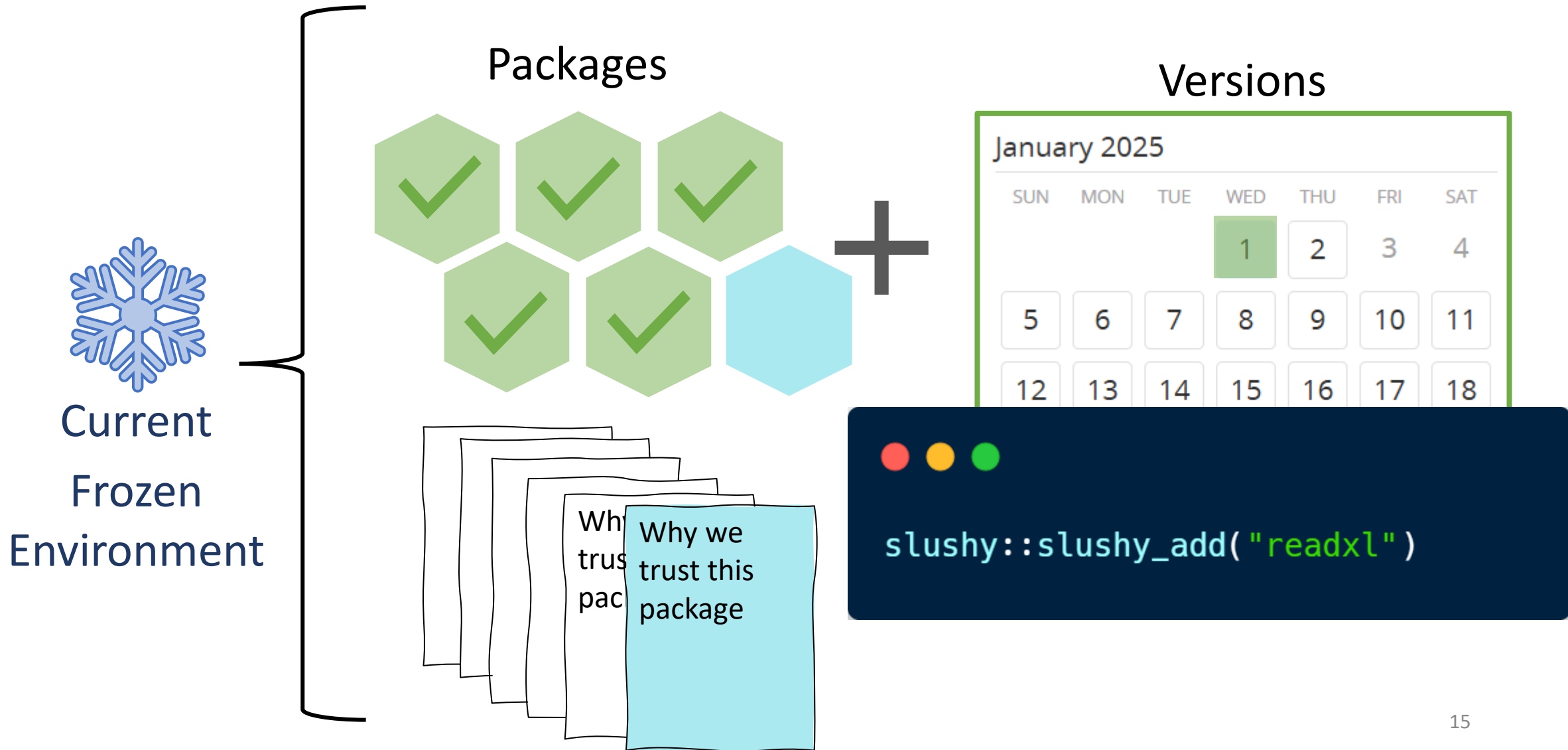
Kick-Off {slushy} Environment



```
> slushy::slushy_init()
```

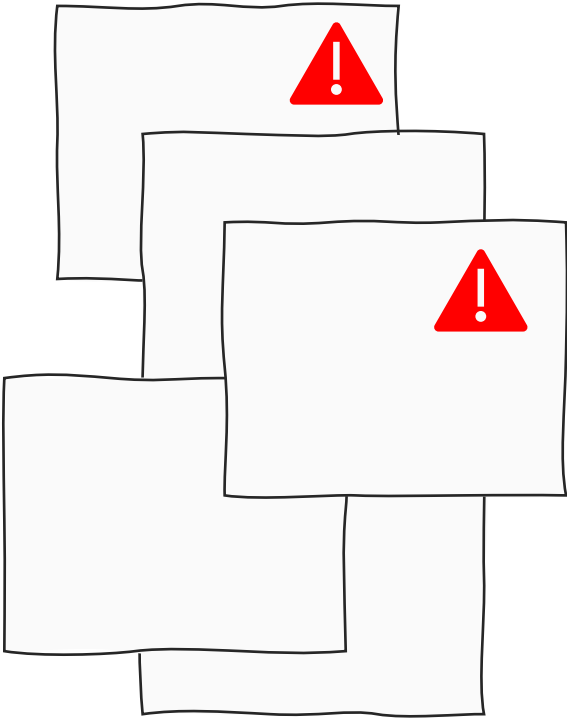
```
✓ Installing `dplyr` ... success (version 1.1.4, cran/2025-01-01)  
✓ Installing `tidyr` ... success (version 1.3.1, cran/2025-01-01)  
✓ Installing `ggplot2` ... success (version 3.5.1, cran/2025-01-01)
```

Augment as Needed



Detect Use of Non-Agreed Upon Packages

.R files



— Checking slushy sync status —

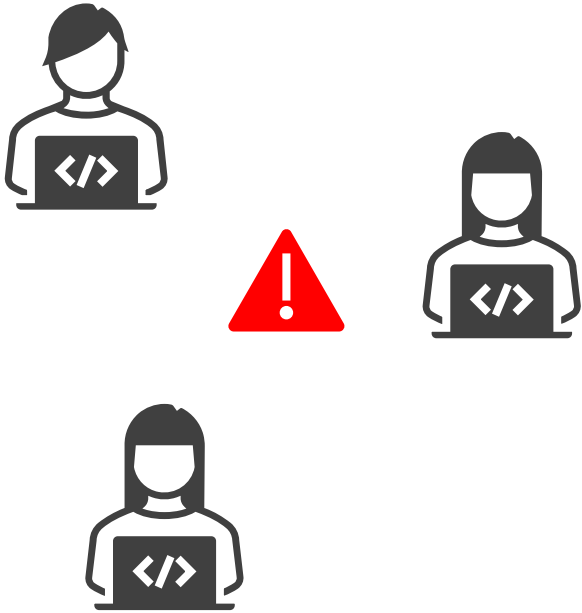
! The following packages are being used in the project but are not part of the agreed-upon set:

reshape2:

my_project/code/program_01.R

✓ Local environment is in sync with lockfile.

Ensure Synchronicity Between Team Members

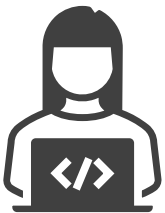
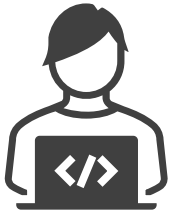


— Checking slushy sync status —

✓ All packages used in the project are part of the agreed-upon set.

! Local environment is out of sync with lockfile.
Use `slushy::slushy_sync()` to sync.

Easily Course-Correct



```
> slushy::slushy_sync( )
```

— Checking slushy sync status —

- ✓ All packages used in the project are part of the agreed-upon set.
- ✓ Local environment is in sync with lockfile.

Produce Artifacts for Reproducibility

```
renv.lock

{
  "R": {
    "Version": "4.4.1",
    "Repositories": [
      {
        "Name": "RSPM",
        "URL":
"https://packagemanager.posit.co/cran/2025-01-01"
      }
    ]
  },
  "Packages": {
    "MASS": {
      "Package": "MASS",
      "Version": "7.3-60.2",
      "Source": "Repository",
      "Repository": "CRAN",
      "Requirements": [
        "R",
        "grDevices",
        "graphics",
        "methods",
        "stats",
```

```
-----
                        Slushy Log Report
-----

— Slushy environment status
✓ Local environment is in sync with lockfile.

— Package Version Mismatches (Installed vs CRAN Snapshot)
      pkg version_inst version_avail recommended_or_base version_match
1  slushy   0.5.2.9000          <NA>          <NA>          NA

Note: `slushy` and `renv` are expected

— Agreed-Upon Packages Used
i Agreed-upon packages that are being used in code: 2
[1] "dplyr" "tidyr"

— Agreed-Upon Packages Not Used
i Agreed-upon packages that are not being used in code: 3
[1] "ggplot2" "readxl" "slushy"

— Changes to Agreed-Upon Packages
i Agreed-upon packages added following slushy initialization:
• readxl
i Agreed-upon packages removed following slushy initialization:
None

— Used Packages Outside the Agreed-Upon Set
None

✓ Summarized report generated successfully.
```

Risk is context-specific



Let's keep our eyes ahead



Photo by [Beau Runsten](#) on [Unsplash](#)

Thank you!



<https://gsk-biostatistics.github.io/slushy/>