



# Introducing pharmaverse & admiral

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*CDISC COSA Hackathon Kick-off: 26th Jan 2023*





*clinical reporting  
(CRF -> Submission)  
forms a small part of  
a large chain in  
bringing a treatment  
to patients*



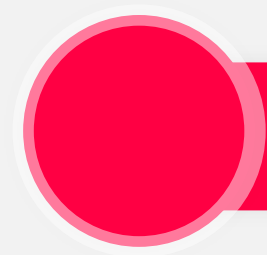
*this space can be  
considered “post-  
competitive” - as it is  
our treatments that  
set us apart*

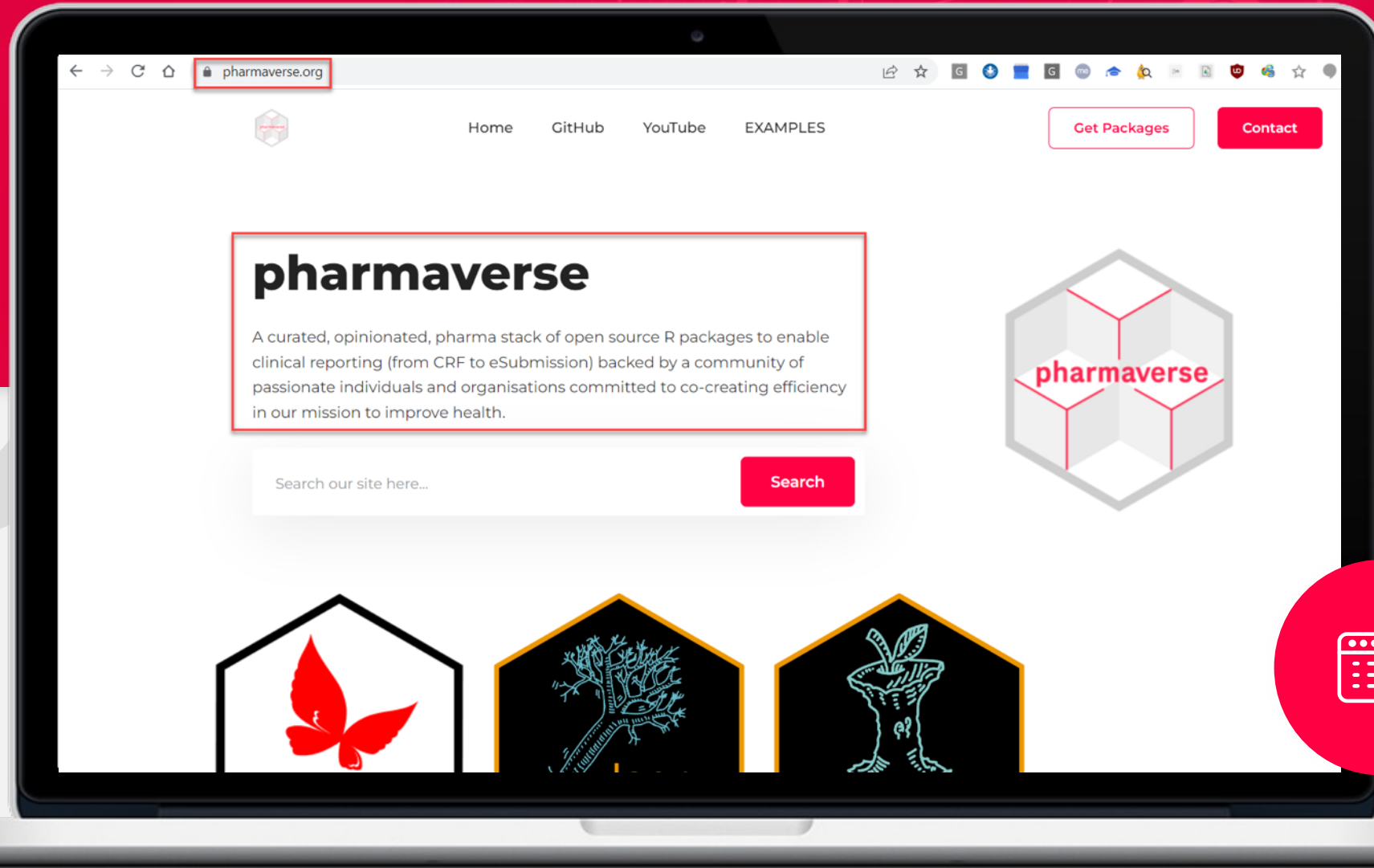


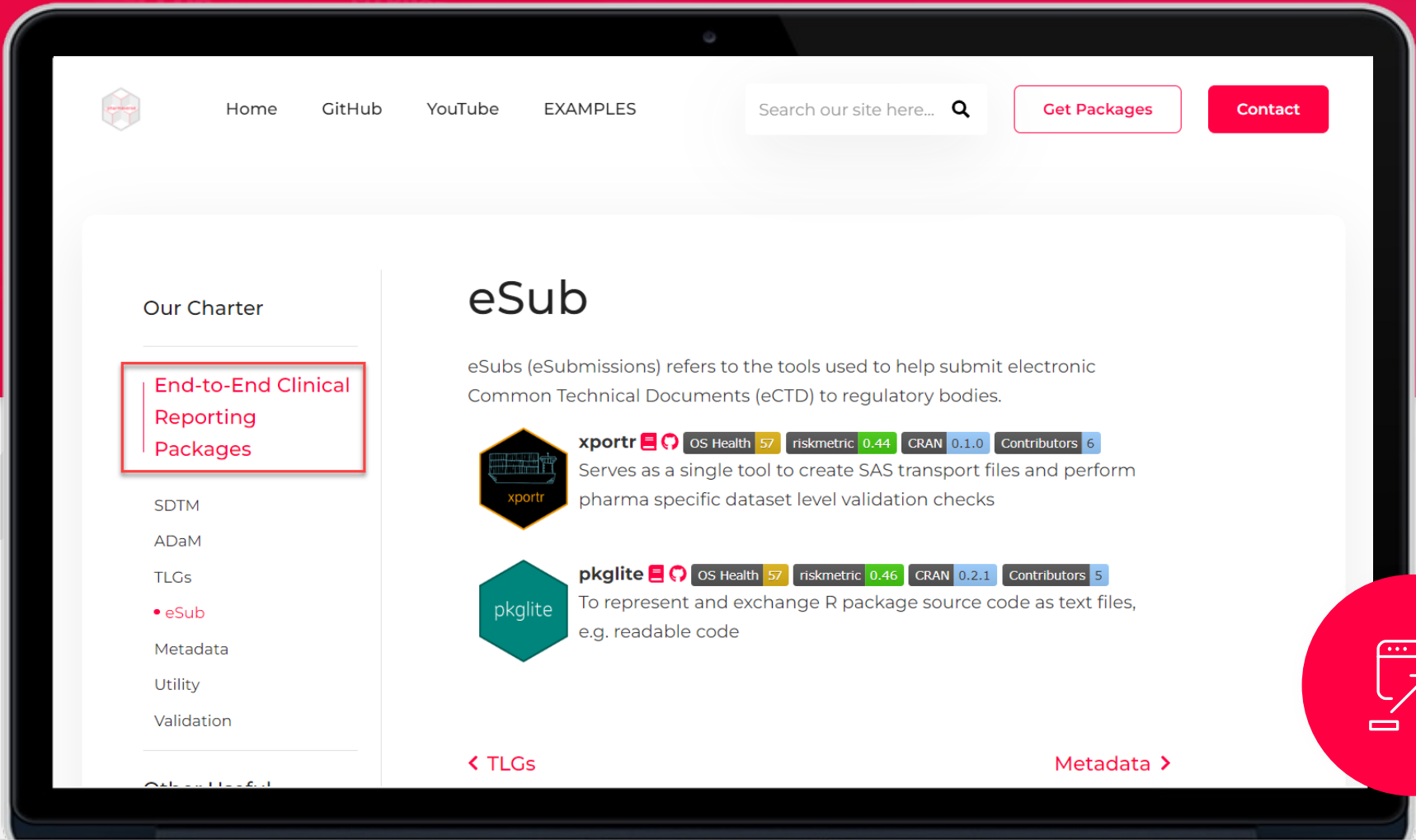
*thanks to CDISC we  
have industry  
standards that mean  
we all face the same  
challenges*



*we have much more  
to gain (than to lose)  
through industry  
collaboration around  
open source*







Our Charter

End-to-End Clinical Reporting Packages

- SDTM
- ADaM
- TLGs
- eSub
- Metadata
- Utility
- Validation

# eSub

eSubs (eSubmissions) refers to the tools used to help submit electronic Common Technical Documents (eCTD) to regulatory bodies.



**xportr** OS Health 57 riskmetric 0.44 CRAN 0.1.0 Contributors 6

Serves as a single tool to create SAS transport files and perform pharma specific dataset level validation checks



**pkglite** OS Health 57 riskmetric 0.46 CRAN 0.2.1 Contributors 5

To represent and exchange R package source code as text files, e.g. readable code

< TLGs

Metadata >



← → ↻ ⚠ Not secure | examples.pharmaverse.org/data/adsl/

pharmaverse

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1. Data

Create ADSL

2. TLGs

3. IDD/Apps

Clear History

Source code

Main pharmaverse website

Create ADSL Edit

The four packages used with a brief description of their purpose are as follows:

- `{metacore}`: provides harmonized metadata/specifications object.
- `{metatools}`: uses the provided metadata to build/enhance and check the dataset.
- `{admiral}`: provides the ADaM derivations.
- `{xportr}`: delivers the SAS transport file (XPT) and eSub checks.

It is important to understand `{metacore}` objects by reading through the above linked package site, as these are fundamental being able to use `{metatools}` and `{xportr}`. Each company may need to build a specification reader to create these from their source standard specification templates.

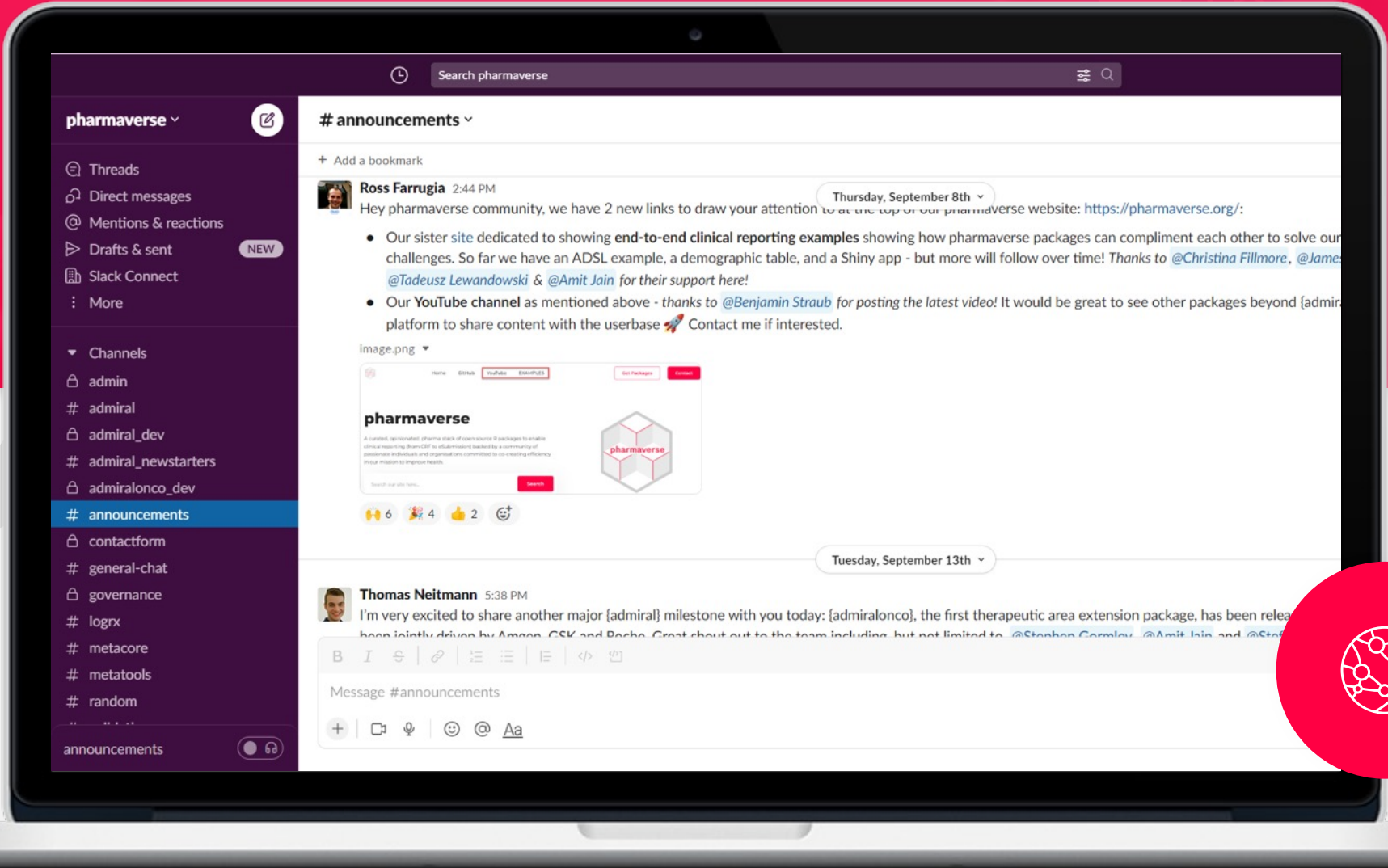
## Load Data and Required pharmaverse Packages

The first step is to load our pharmaverse packages and input data.

```
options(repos = c(
  pharmaverse = 'https://pharmaverse.r-universe.dev',
  CRAN = 'https://cloud.r-project.org'))

library(metacore)
library(metatools)
library(admiral.test)
library(admiral)
library(xportr)
```









# Imagine a world where...



*every company (large & small), charity, academic group etc all have access to FREE solutions to support creating a clinical submission*



*regulators receive more consistent packages delivered using trusted code, thus speeding up approval times and patient access*



*less resource intensive clinical reporting leads to individual data science talents being freed to help generate new scientific insights*



*our regulatory pathways are revolutionised opening the doors for less paper-based submissions via interactive tools*



***we achieve all of the above TOGETHER!***





# useful links...



## **slack channel:**

<https://pharmaverse.slack.com/>

(use this [link](#) to join our community, if you don't already have access)



## **website:**

<https://pharmaverse.org/>



## **examples:**

<http://examples.pharmaverse.org/>



## **open pharma:**

<http://openpharma.pharmaverse.org/>



## **youtube:**

<https://www.youtube.com/channel/UCxQFEv8HNqM01DXzdQLCy6Q>



## **linkedin:**

<https://www.linkedin.com/groups/9126149/>

