



# Enabling R in Lundbeck

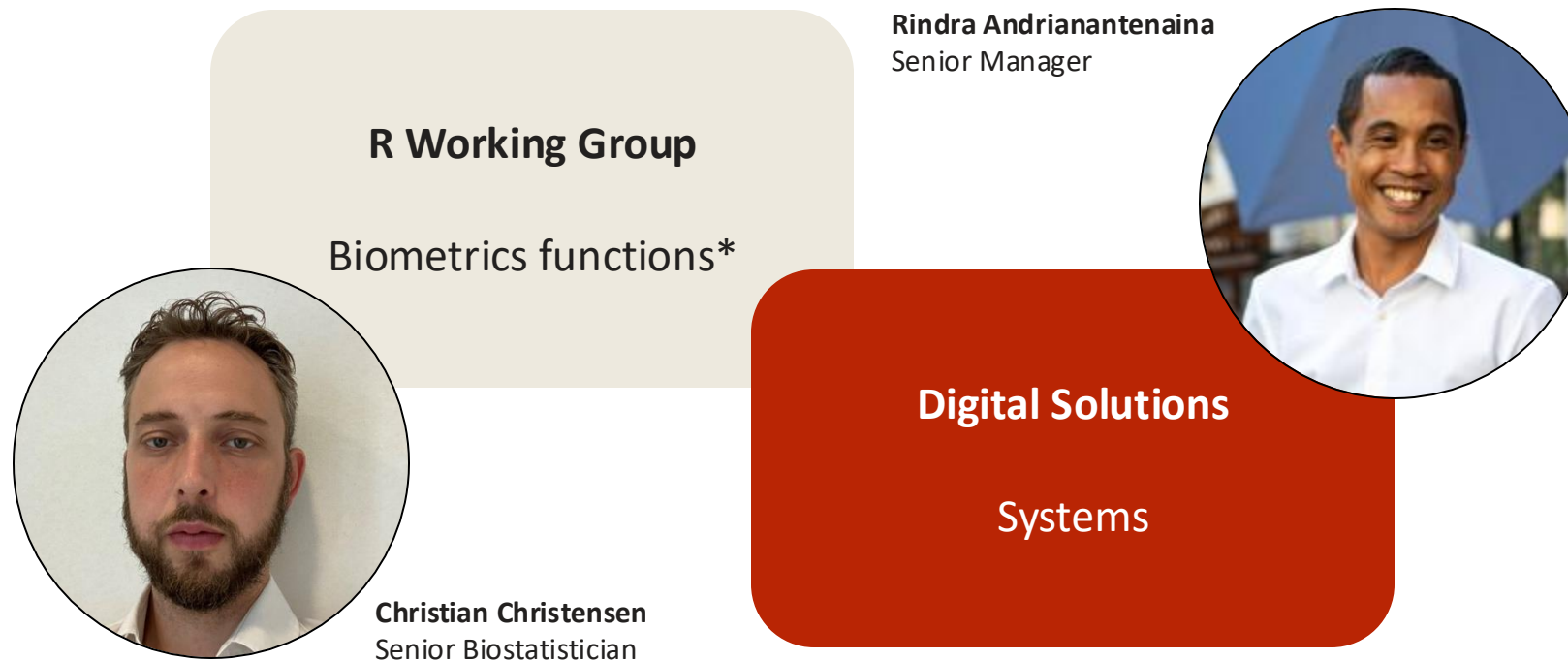
A Journey Towards Open-Source

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# Setting the Scene

The R Working Group started in 2022.

Motivation: Utility, new talent & specific trial need.



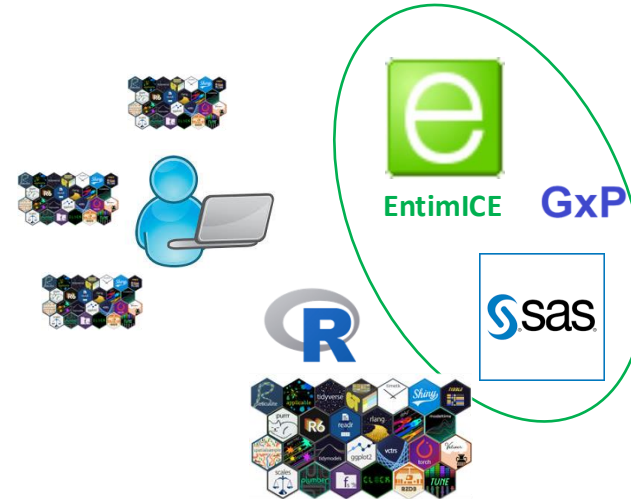
\*Biostatistics, Data Science and Statistical Programming

# Starting Setup

- EntimICE – GxP
- R server with set of pre-installed packages (not validated) and used for exploratory analysis
- Very old version of R which was almost incompatible with all the most used R packages.

## Specific to R integration

- R packages are managed centrally on the R server(s) and shared across all users
- End-Users can install their own packages. The packages are automatically uninstalled at the end of the R session



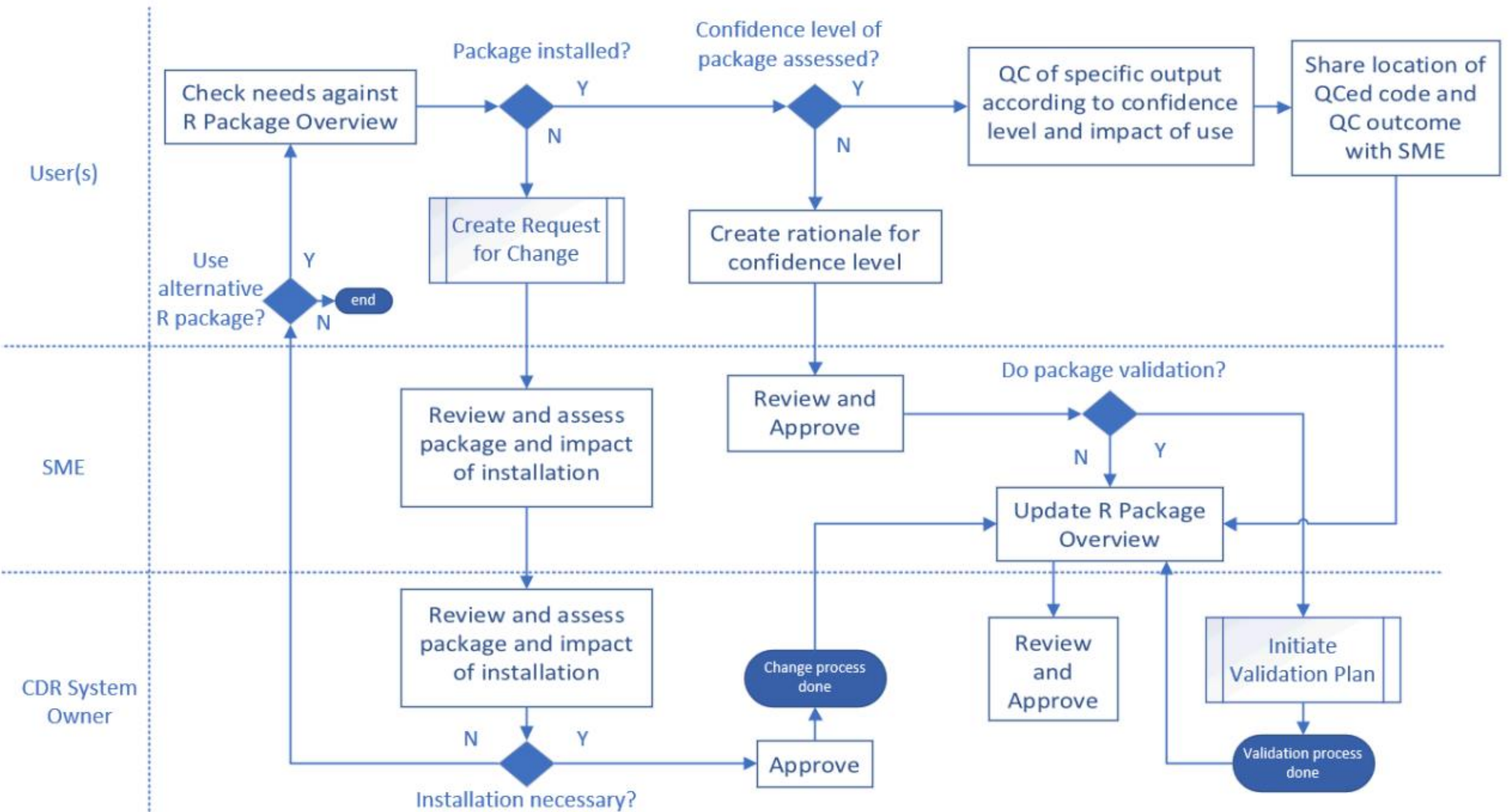
## How did we achieve that ?

- Upgrade of R version
- Define a set of packages that will be installed as part of the R upgrade
- R installation : Dated snapshot & software with version-control (for reproducibility)
- Remove the possibility to remove/update existing packages and to install new packages from the infrastructure level
- Audit Trail functionality in EntimICE extended to R
- Write the validation plan, tests (test strategy described later) and the validation report
- Go-Live Q4 2023



# How do we operate ?

- Setup a process for managing R upgrades and packages in place and formalized that in a R management SOP
- The SOP outlines the operation and maintenance of the R packages in terms of roles and responsibilities
- Training of SOP to the end-users + Best practices
- Maintain an R Package Overview document



# R Package Management

## Package Selection



- R user input & trial need
- Broad installation

Restrictions: CRAN & snapshot

## Validation/QC

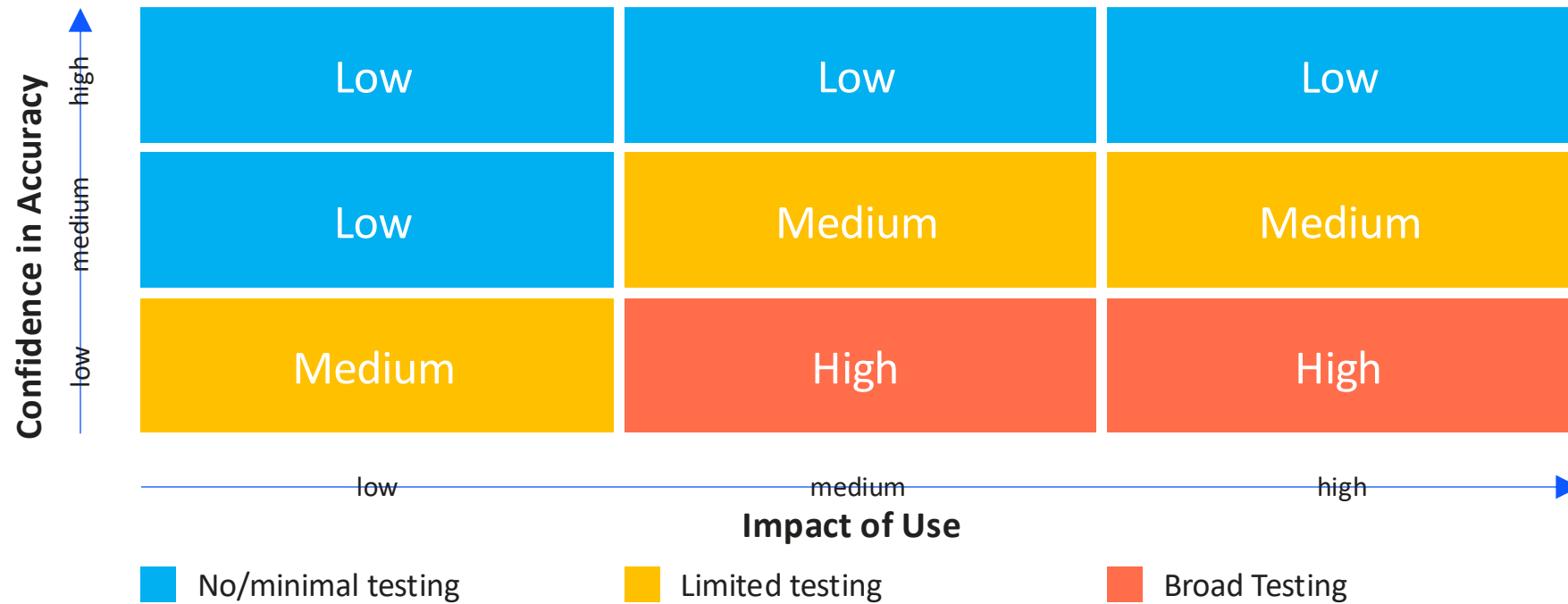


- Scope: Directly used packages
- Risk-based approach

QC by independent implementation

# Validating a Package

## Risk assessment



Adapted from [Trancelerate Modernization of Statistical Analytics/](#)  
Confidence covers complexity, maintenance, community usage and existing testing.



# Use cases

Bayesian Statistics  
using rjags & rstan

Vendor Analyses  
PKNCA inhouse

# Challenges

Past, future and present

## Snapshot:

- Availability
- New packages

## SAS/R:

- Standardisation
- Skill-base

## Setup:

- IT/LoB gap
- R version
- Shiny

# Q&A

## Resources:

- [R Validation Hub](#)
- [FDA Software Clarifying Statement](#)
- [Transcelerate Modernization of Statistical Analytics](#)
- [R: Regulatory Compliance and Validation Issues](#)

Lundbeck

