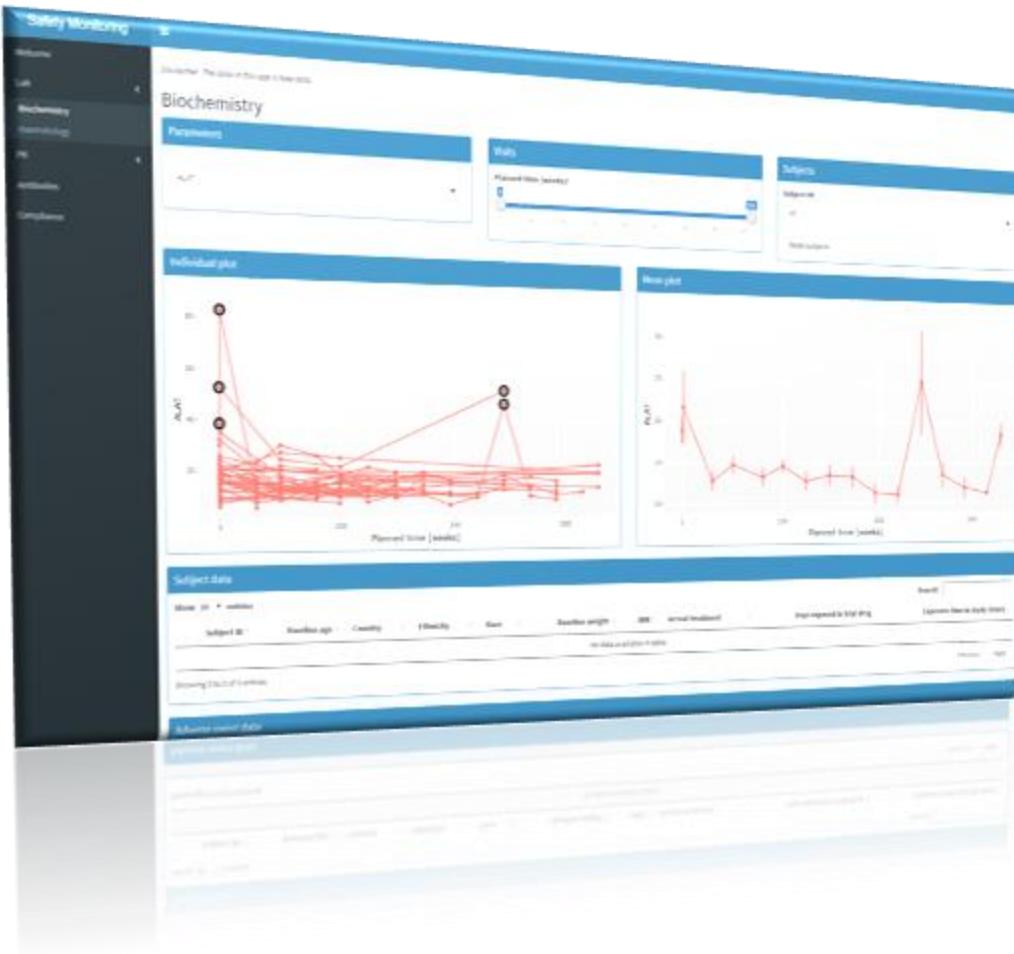




Ongoing Safety Monitoring using R-shiny

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03/09/2021

Presenters



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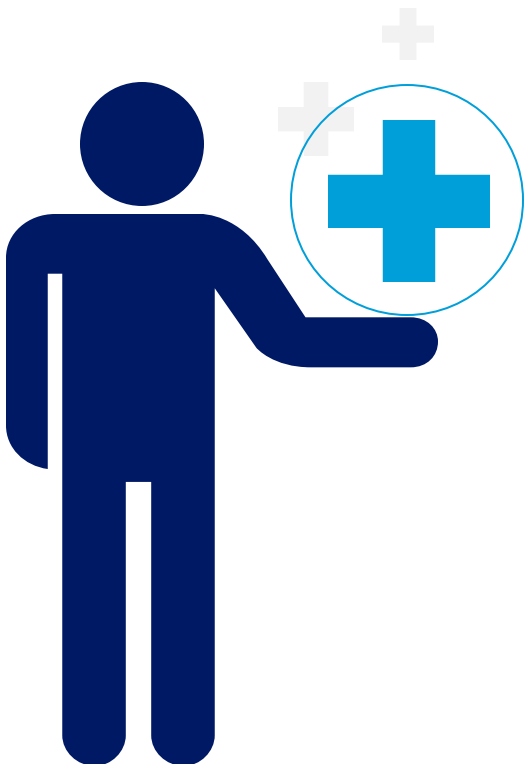
Views and opinions expressed are those of the speaker and not necessarily Novo Nordisk.

Agenda



Motivation

Safety is key!



Challenges

- Complex and huge amount of data
- Get overview to better evaluate safety on individual and trial level

Benefits with visualisation tools

- Better overview of data
- Possible to continuously evaluate safety data
- Greater possibility of data exploration
- Data cleaning purposes

Project description

Haemophilia disease

- Rare blood disorder
- 400.000 people world wide
- Potentially in mild
- Missed coagulation factor
- Symptoms include extended bleeding after surgery and trauma, spontaneous bleeds without a known cause and damaged joints

Haemophilia trials

- Trials are often very long (~5-10 years)
- Few subjects in a trial (~50)
- Subjects are very conscientiously
- Close monitoring of patients → lots of data

Data

Presentation of data

- Data from two ongoing paediatric clinical trials
- Legacy data model (no SDTM or ADaM)
- Focus on safety data



Disclaimer: For the purpose of this demonstration we have created ***fake*** data, so no data from ongoing clinical studies will be shown when demonstrating the application.



Constructing the app – getting started

Our starting point

- Prior experience with R from university
- No prior experience with R shiny

Packages

- Shiny
- shinydashboard
- Haven
- Plotly



Building the app

- 3 basic components:
 - `ui`: user interface
 - `server`: specifies behaviour of the app
 - `shinyApp`: execution

- Example:

```
ui <- fluidPage(  
  )  
server <- function(input, output, session) {  
  }  
shinyApp(ui, server)
```

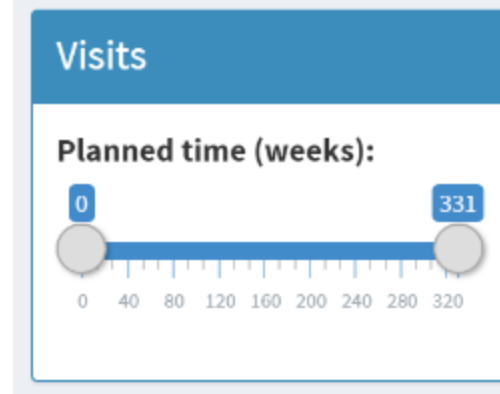
Constructing the app – functionalities

Reactive app: output automatically reacts to new user input

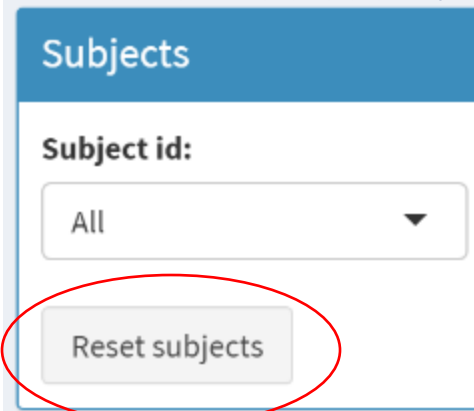
About the process

- Data manipulation and app are kept separately
- Create minimal viable product
- Iterative process, i.e. defining app together with stakeholders and their needs

Slider:

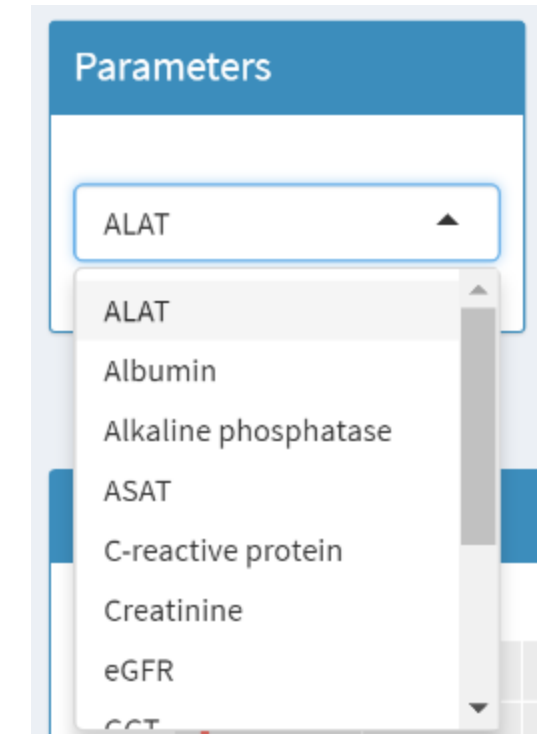


Action button:



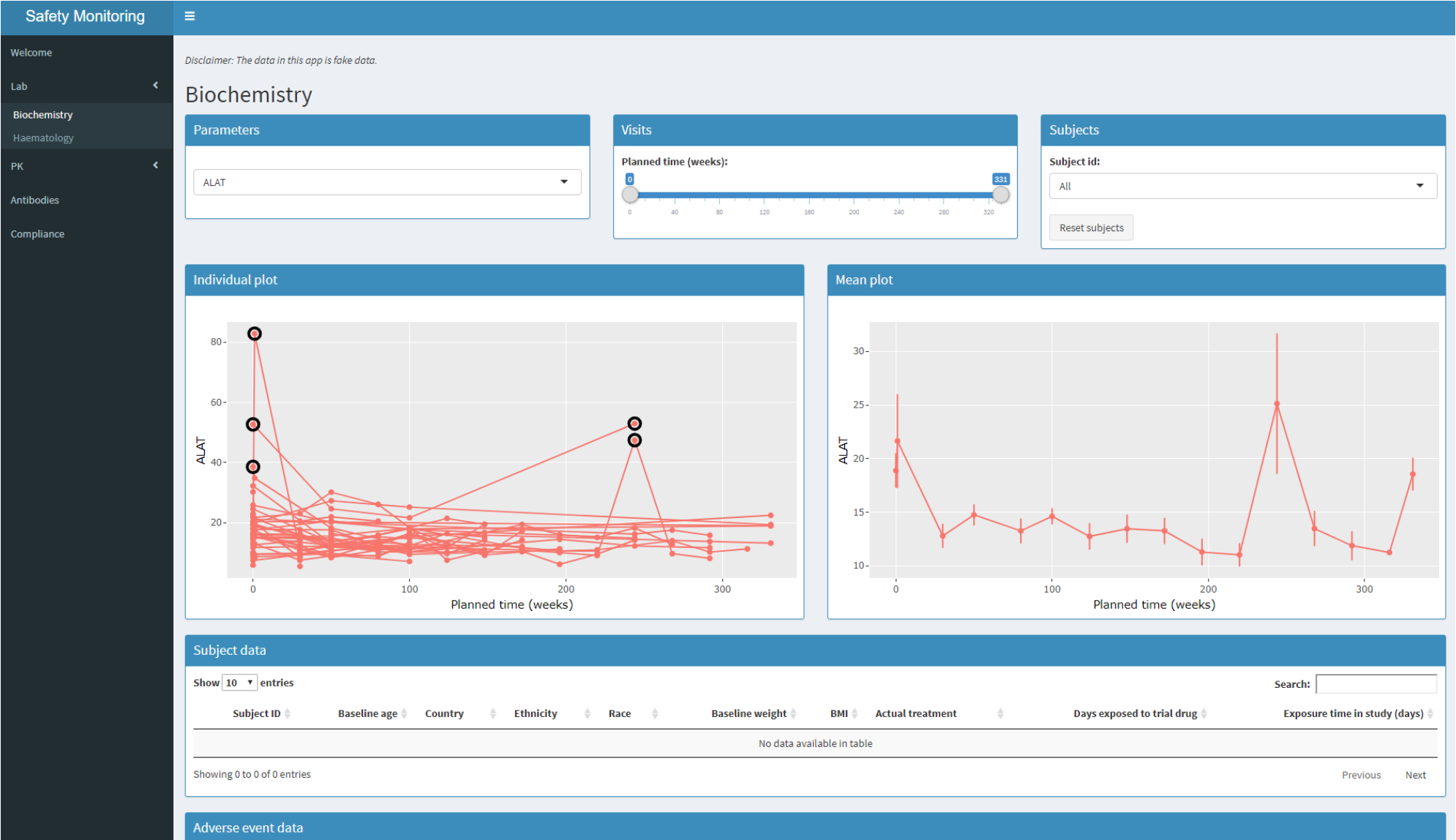
A form titled "Subjects" with a "Subject id:" label and a dropdown menu showing "All". Below the dropdown is a button labeled "Reset subjects", which is circled in red.

Drop down list:



A dropdown menu titled "Parameters" showing a list of parameters: ALAT, Albumin, Alkaline phosphatase, ASAT, C-reactive protein, Creatinine, eGFR, and GGT. The "ALAT" option is currently selected and highlighted.

Demonstration





Future work

This App

- Feedback from stakeholders has been really positive!
- Keep developing the app in collaboration with stakeholders
- Experimental and work in progress

Other Novo Nordisk initiatives

- Developing more standardised tools – to be used across different projects
- Incorporation of tools across skill areas

Question – will the future be: *Selected static outputs for external communication and everything else in an app?*

Acknowledgements

We would like to also take time to thank some people who have contributed to this project:

- Christian Haargaard Olsen (Senior Statistical Programmer)
- Helle Holst (International Medical Director)



Thank you for listening!

