



A Review of Open Source in New Drug Applications: Current Trends

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Hello!



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I started a list of submissions that use open source in 2023





✳ github.com/philbowsher/Open-Source-in-New-Drug-Applications-NDAs-FDA 🌟





💣 It shows open source has been used in submissions... 📖

📢 ...for a long time (2007)





Many Pharmas are using R for Submissions





☀️ ...And With Various R versions 📖
📢 like **UCB & Intercept Pharmaceuticals**



>

🌻 ...And the FDA uses R as seen in [Here](#) 📖

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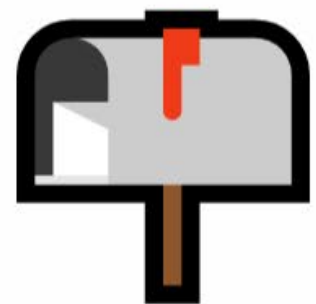
- 🔔 **R has been used for Pk/PD in Submissions for a while**
- 📢 **This is a great place to start or to find R programmers**





 Now Pharmas are using it for Stage 3 work... 
 like **UCB & Intercept Pharmaceuticals**





And Pfizer...



...which list R 55 Times in this NDA





🎨 And Pharmas are using R for RWD Submissions 📖

🔍 **Like Astellas Pharma US in this NDA**





And groups are using Python and other tools for submissions





Like Bayer Healthcare [here](#)





 Discuss availability of using open source prior to submission 
 **& submit sample data & codes if applicable**





As Astellas did with tacrolimus



"FDA Response to Question 3c: We agree with the program submission using R markdown"





 **Exciting to see RMD used too!** 

 **which opens the door for multi-lingual support via Quarto**





Still looking for Shiny & or Interactive HTML



Return on Investment (ROI)

- Partnerships and collaborations with external partners
- Streamlined Workflows
- Talent out of university more likely to know open-source programming languages
- Latest developments more rapidly
- Switch between languages and contexts more easily
- Time savings in creating standard TLGs
- Time savings in creating customized TLGs
- Access to free solutions to support creating a clinical submission

OS in Pharma & R in Pharma!



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R Validation Hub!



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 Implementing a Risk-Based Approach to R

 pharmar.org

Pharmaverse!



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R Submissions Working Group!



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 Ning Leng & Hye Soo Cho. R pilot submissions to FDA

 submissions-wg

Feel free to send any I missed!



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