

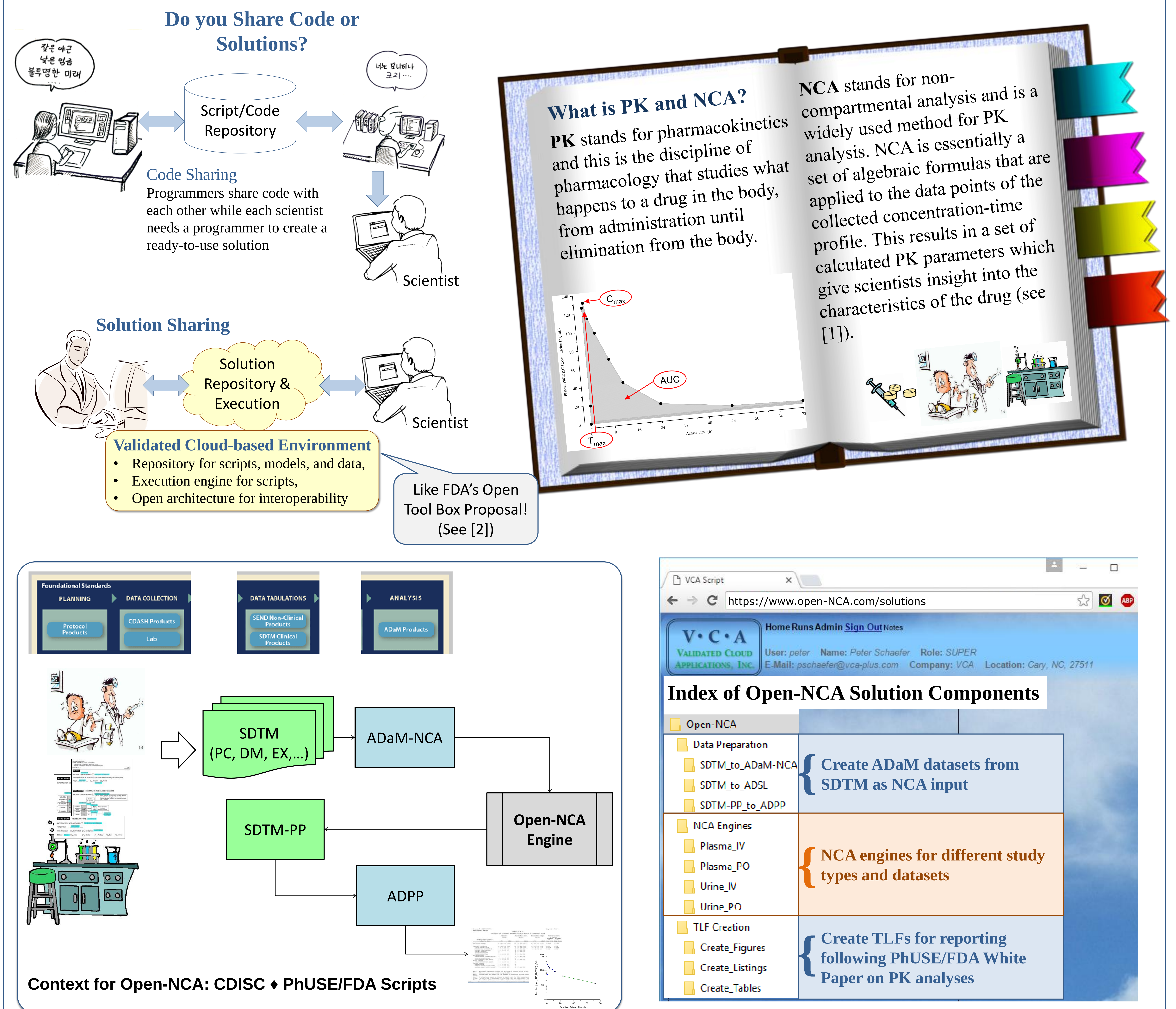
Open-NCA – R Scripts for CDISC-based Pharmacokinetic Analysis

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Pharmacokinetic analysis is a key method during drug development to investigate what happens to the drug in the body after dose administration. Today, non-compartmental analysis (NCA) is still one of the most widely used methods for PK analysis because of its simplicity and ease of use from study data preparation to reporting.

This poster presents a concept for an open source alternative to commercial NCA software for pharmacokinetic analysis of clinical and pre-clinical study data. It is assumed that the study data are organized and formatted according to CDISC standards and that the primary NCA output will be a SDTM-PP domain dataset containing the calculated PK parameters. As an extension to the core NCA implementation, additional scripts would cover typical data preparation tasks as well as reporting on results, i.e., the creation of tables, listings, and figures.

The time is right for this kind of solution because NCA is very much a well-established solution that simply should be a shared commodity within the industry. In addition, there is a paradigm shift that already changes the traditional supplier-consumer relationship between software vendors and pharmaceutical / biotech companies, and new technology-driven companies will provide the industry with more efficient and cost-effective solutions than traditional software companies.



Conclusion

The timing is right for developing and sharing validated NCA solutions to streamline and optimize PK analysis and reporting workflows.

The components – NCA algorithms, data standards, analyses, technology – are available and can be integrated.

If you are interested to learn more, to contribute, or to benefit from this effort, please contact me at pschaefer@vca-plus.com.

References

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- [2] About FDA's Open Tool Box proposal, see: <http://www.fda.gov/downloads/Drugs/NewsEvents/UCM209100.pdf>