

Introduction

The creation of a submission-ready scientific report can be a tedious task of manually copying and pasting figures into word processors, transcribing numbers into table cells, etc. Moreover, should the report require updates due to reviewer's comments or if the analysis needs to be rerun (e.g. due to a data update), the entire procedure needs to be redone and the resulting report subject to further quality control (QC). We present a community effort to make reporting simple, reproducible, and user-friendly using a customized setup based on the document processing system LaTeX. The latter is already the golden standard for scientific journals and in academia, but it has not yet been widely adopted in the pharmaceutical industry.

The PharmTeX Setup

The LaTeX setup allows the user to create a publishable PDF document directly from figure image files and tables from CSV text files. A predefined template has all submission-ready standards built into it and is therefore fully compliant with regulatory expectations. Numbering of and references to sections, figures, tables, citations, etc. are automatically updated as the document is written. The time required to create and QC the report is reduced from weeks to days, and updating it to a matter of minutes or hours. No prior knowledge of LaTeX and only a few hours of training is required for anyone to get started. The basis for this platform was originally developed by Global Pharmacometrics at Pfizer and is being implemented to improve reproducible research and increase efficiency in reporting. It is currently being converted into a more flexible platform named PharmTeX that allows customization to fit specific reporting needs, e.g. modeling reports, study reports, protocols, etc. It will support plugins, e.g. written in perl, to allow integration with any Windows and Linux-based systems. The platform will reside on Github at for anyone to access: <https://github.com/hove99/PharmTeX>

Conclusions

Using a LaTeX-based system for reporting substantially reduces the overhead in creating submission-ready reports and in turn can improve the report quality and reproducibility. PharmTeX will make the utilization of LaTeX much simpler and more easily accessible to the pharmaceutical industry and academia. An open-source platform ensures continuous community-based maintenance.

Acknowledgements

We would like to acknowledge Kaori Ito, Lynn McFadyen, Paula Burger, Luke Fostvedt, and Mike K. Smith from Global Pharmacometrics, Pfizer, Inc. for their invaluable contributions to the development of the PharmTeX reporting tool.

Source Code

```
\documentclass[asr]{PharmReport}

\projectcode{A123}

\drugname{DRUG-1234}

\eqddid{Report Number}

\documentitle{Population Pharmacokinetic Analysis of \DrugName}

\documentdate{07 JUN 2016}

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}

\begin{document}

\section{OBJECTIVES}

Here are a few references: \cite{Hughes2003, Albus2002}. Here is a cross reference to \cref{sec:results}.

\section{RESULTS} \label{sec:results}

Here is \cref{tab:parvalues}:

\pmxtable[1]
{parvalues.csv}
{texcomma}
{LLLL}
{tab:parvalues}
{Final model parameter estimates}
{Final model parameter estimates from NONMEM.}
{}

In \cref{fig:vpc} a \gls{VPC} for the final model is shown.

\pmxfigure
{vpc.png}
{fig:vpc}
{Visual predictive check}
{Visual predictive check}
{}

\references

\end{document}
```

Document Output

A123
DRUG-1234
Report Number

1. OBJECTIVES

Here are a few references: [1, 2]. Here is a cross reference to Section 2.

2. RESULTS

Here is Table 1:

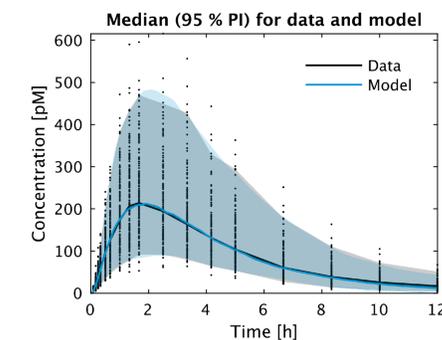
Table 1. Final model parameter estimates

Parameter	Expected	95 % CI	RSE%
θ_{KA} [min^{-1}]	0.0154	[0.0146; 0.0163]	2.7 %
θ_{KE} [min^{-1}]	0.0987	[0.0930; 0.104]	2.9 %
θ_V [L]	15.3	[14.6; 15.9]	2.2 %
ω_{VARKA} [min^{-2}]	0.0346	[0.0235; 0.0458]	16.3 %
ω_{VARKE} [min^{-2}]	0.0547	[0.0385; 0.0708]	14.9 %
ω_{VARV} [L^2]	0.0387	[0.0268; 0.0506]	15.6 %
σ_{PROP} [#]	0.00364	[0.00333; 0.00395]	4.3 %

Final model parameter estimates from NONMEM.

In Figure 1 a visual predictive check (VPC) for the final model is shown.

Figure 1. Visual predictive check



Visual predictive check

3. REFERENCES

- [1] Hughes C, Kumari V, Soni W, Das M, Binneman B, Drozd S, O'Neil S, Mathew V and Sharma T, 2003, Longitudinal study of symptoms and cognitive function in chronic schizophrenia. *Schizophrenia research* **vol. 59**: 137–146.
- [2] Albus M, Hubmann W, Scherer J, Dreikorn B, Hecht S, Sobizack N and Mohr F, 2002, A prospective 2-year follow-up study of neurocognitive functioning in patients with first-episode schizophrenia. *Eur Arch Psychiatry Clin Neurosci* **vol. 252**: 262–267. URL <http://dx.doi.org/10.1007/s00406-002-0391-4>