

L^AT_EX-based report writing: 10 years' experience from Sanofi's M&S group in Germany

Thomas Frank¹, Ashley Strougo¹, Klaus Lindauer¹, Diether Rueppel¹, and Heiner Speth²

¹Sanofi, R&D Operations/Translational Medicine and Early Development (TMED), Pharmacokinetics, Pharmacodynamics and Metabolism Germany, M&S
²Sanofi, R&D Operations/TMED, Global Applications

thomas.frank@sanofi.com



Background

The writing of population analyses reports fulfilling the specifications of submission readiness is a time-consuming process highly subjective to human errors. In order to ease this process and diminish the likelihood of error we have been using the document preparation system L^AT_EX to write these reports.

Objectives

To share our concept and more than 10 years' experience in using L^AT_EX to write population analyses reports.

Methods

L^AT_EX (TeX Live) has been in use internally for about 20 years to write population analysis reports. The templates were maintained and further developed over the years in order to enable newer functions and improvements of TeX Live, to comply with regulatory requirements, and to ensure simplification that allows less experienced L^AT_EX users to benefit from the template.

- The current template version is based on **scartcl** document class of **KOMA-Script** (TeX Live 2017 for Linux). It essentially consists of one master file that inputs multiple sub-files representing mostly the textual content of each section of the report (Fig. 1). Each file is provided with example text and clear guidance to allow modifications (Fig. 6). In general, users only need to modify the sub-files to insert specific information on the analysis performed.
- Future-safe TeX Live packages like **biblatex/biber** and **glossaries** manage bibliographic data and/or definitions of terms/abbreviations (Fig. 5).
- The rendition of one single PDF file (Fig. 7), including creation of reference list and list of abbreviations proceeds automatically by using **make** program.
- Usage of a **git repository** to enable shared and version-controlled template maintenance.

Implementation

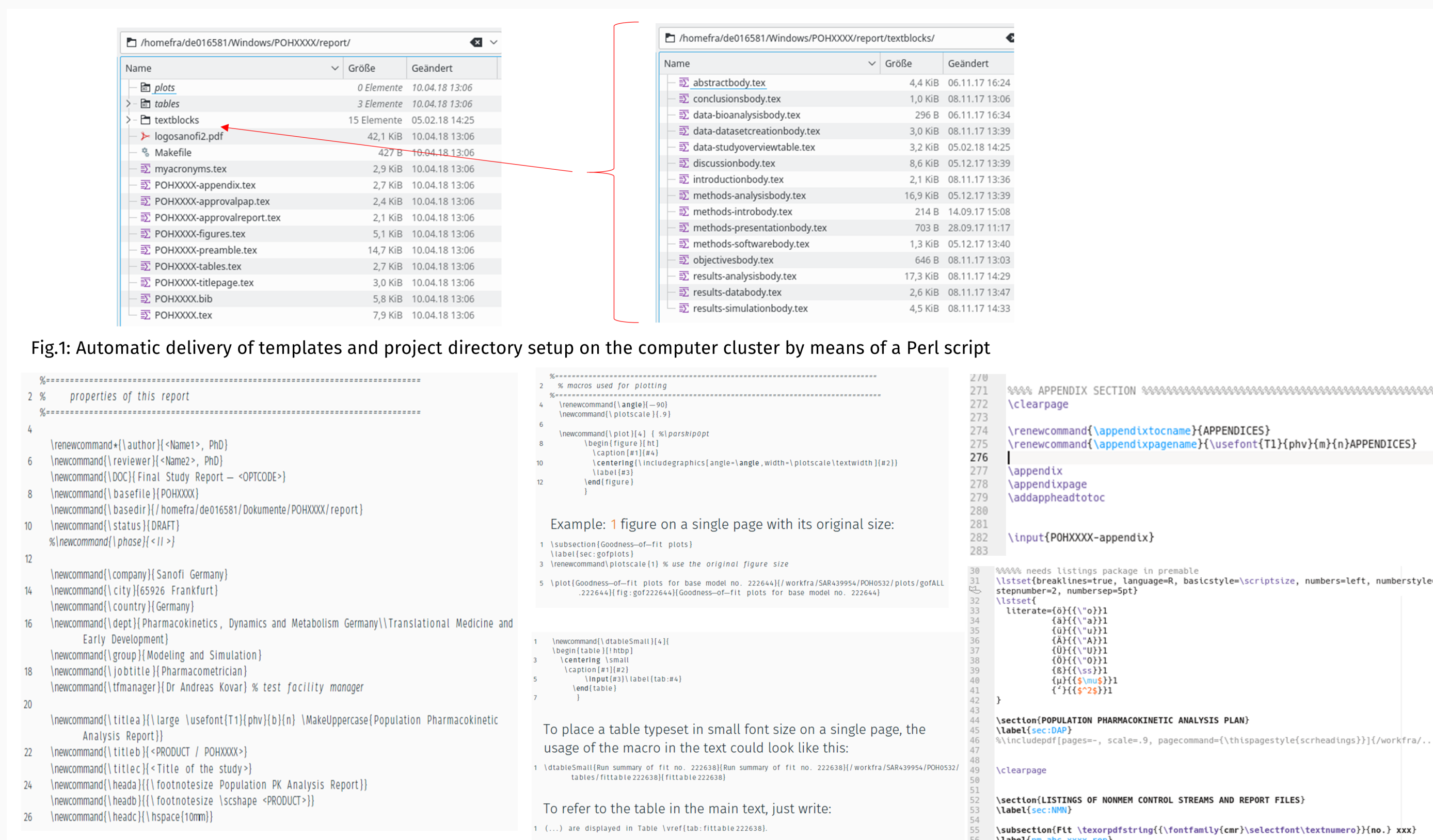


Fig.1: Automatic delivery of templates and project directory setup on the computer cluster by means of a Perl script

Fig.2: Document properties managed at a central location (POHXXXX-preamble.tex)

Fig.3: Macros to insert figures and tables (POHXXXX-figure.tex)

Fig.4: Appendix created along with the main text (upper panel) and source code of POHXXXX-appendix.tex (lower)

Output



Fig. 6: Example text with guidance (introductionbodytex)

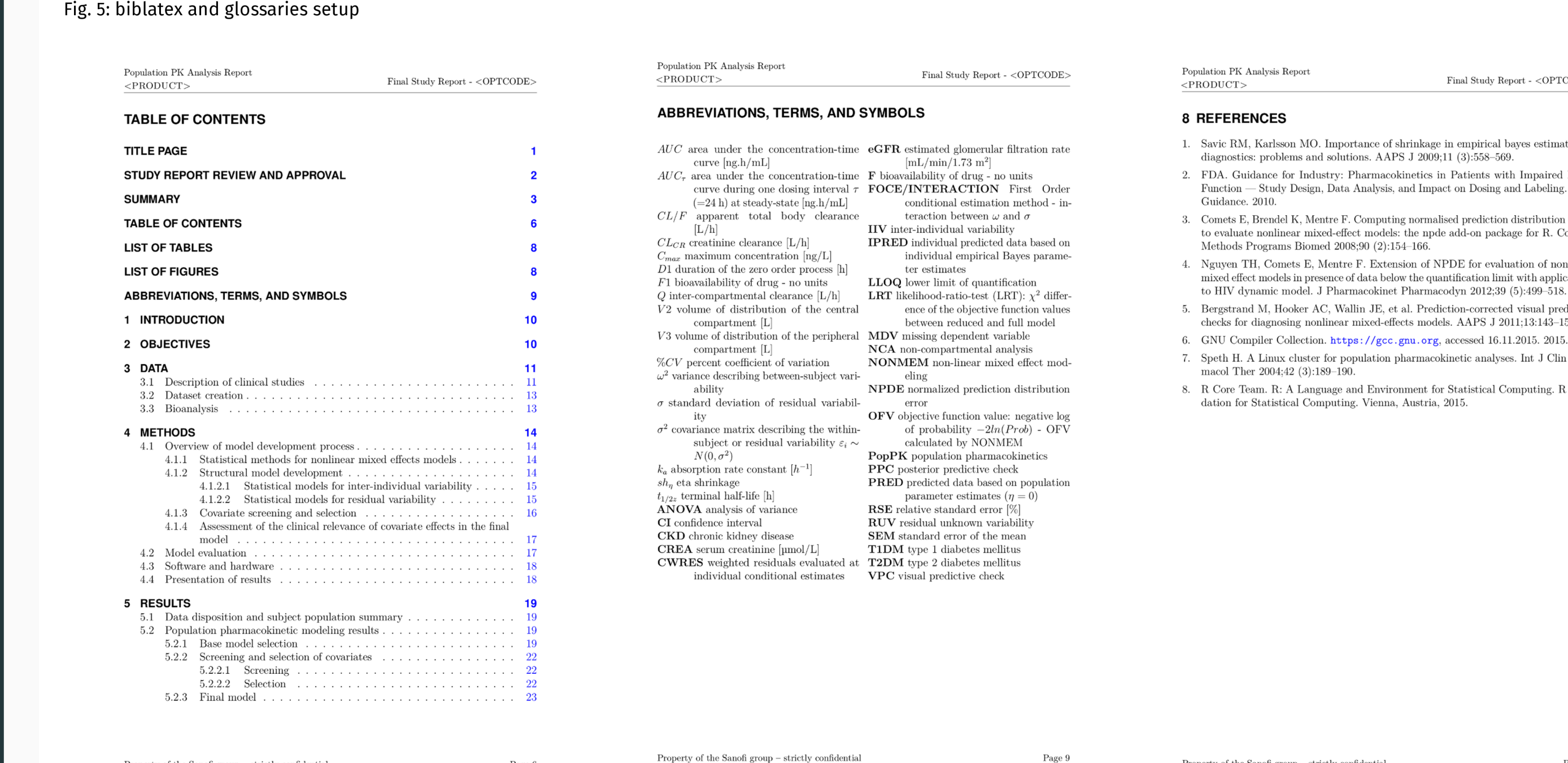


Fig. 7: Example pages of PDF output

Results

- Over the last 10 years, 28 reports have been issued in the corporate document management system, whereof 27 are part of Common Technical Documents (CTDs).
- The experience made can be summarized as follows:

Advantages	Disadvantages
> Over the years L ^A T _E X has remained open-source software and found to be very stable	> For reviewers: no MS Word version available to allow review using 'track changes', though almost fully overcome by the advances of tools for commenting in PDF documents
> Facilitating the work of the author, quality control reviewer and the coordination group responsible for the submission readiness of the report	
> Easiness in insertion and updates of tables, figures (Fig. 3) and creation of the extensive appendices (Fig. 4)	
> No formatting issues (eSub compliance!) or rework to be done by document coordination group within Sanofi	
> Easy adaptations due to changes in corporate layout guidelines.	
> Easy preparation of slides (L ^A T _E X Beamer package)	

- For successful implementation of L^AT_EX the team should have at least one expert on the topic who offers comprehensive user support.

Conclusions

Our concept for the report template was developed in a way that proved to be simple enough to allow non experienced L^AT_EX users to benefit from it. The advantages of using L^AT_EX-based report writing are found to outweigh the few disadvantages. In general, our group has a very positive experience in using L^AT_EX-based report writing, and we tend to continue using it in the future.