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Measuring the Benefits of Standards

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ABSTRACT

It is a widely-held belief that standardization enhances efficiency and allows for savings in time and resources. However, there is currently not a great deal of evidence available to support this belief.

In Clinical Data and Information Sciences (CDIS) within Roche pRED (Pharma Research and Early Development), we are using a set of standard form templates to collect safety-related data (AE, Lab, Demography, Concomitant meds, etc.). These standard form templates have been used in a large number of studies, but not all. There are various reasons for not using these standards.

The results of an experiment which was set up to provide evidence of the benefits of using standards will be presented. Different testers were approached to build a database which would be set up using the same protocol/schedule of assessments, but would involve different levels of standardization (100% standards used in setup, 50% standards used in setup, and no standards used at all).

The results presented will show the time taken to complete the database, broken down into high-level tasks, and conclusions drawn based on the results.

INTRODUCTION

The Roche “pRED Core Standards II” global library volume was rolled out in Q2/2010. Since then, uptake of standards use has been a little slower than expected. There are many reasons for this which often have basis in study-specific requirements, but can also be simply because previous studies were used as source material by the study team, rather than making the decision to use the core standards.

Within (and outside) pRED CDIS, more evidence than a strong belief is required to prove the case that using standards will increase efficiency and ultimately save money.

This project focuses on measuring the benefits of standards from a Clinical Database Programmer (CDP) perspective and also touches on the Study Data Manager (SDM) perspective. This project has a precise scope which will involve measuring the benefits of standards in database setup.

METHOD

A test plan was developed to assess if and how much standardization benefits efficiency. The test plan was independently reviewed to ensure that the experimental design would not favour the use of standards right from the start.

Three test scenarios were proposed:

- 100% use of pRED Core Standards II volume
- 50% use of pRED Core Standards II volume, 50% non-standard content in study setup
- No use of pRED Core Standards II volume at all. All study setup to be non-standard.

The database system used was Medidata RAVE version 5.6.3, and within this database system it was decided to take advantage of the availability of the Roche RAVE training URL so that strict controls could be placed on the access and user role allowed to the testers.

Three projects were created in the RAVE training URL:

- CSIIEFF000: 100% sourced from pRED Core Standards II volume
- CSIIEFF050: Approximately 50% sourced from pRED Core Standards II volume
- CSIIEFF100: Nothing sourced from pRED Core Standards II volume

In addition to these three projects, the current Roche Core Standards global library volume was copied to the training URL and made available to the testers who required access to it.

Creating each project in RAVE in this way allowed the experimental designers to place strict limits upon the user role and access of each tester. For example, the tester who would not be using any standards was not given access to the Core Standards global library volume on the training URL. Also, none of the testers had any access to other studies on the training URL, so no other study could be used as a copy source. This prevented any copying between the different test scenarios. Note that no quality control of each tester's study build was planned.

Three CDPs with comparable experience levels were approached. When each had confirmed they were willing to participate, each CDP was randomly assigned to a test scenario. Each CDP had a short briefing meeting with the designer of this project, then provided with appropriate documentation, RAVE access and timelines for completion.

Within each test scenario, it was recognized that an identical study design should be planned for as much as possible. Therefore each test scenario would contain exactly 28 specific forms, all of which had been defined in the pRED Core Standards II global library volume. Identical schedules of assessments were designed. With this study design plan in place, the only difference between each test scenario would be the definition of each object in the RAVE database.

In order to provide the testers with appropriate study setup information, the following documentation was created for each test scenario:

- Matrix Design Document (MDD). The MDD is an internal pRED document which is created for all studies, and provides a central reference/source for the protocol schedule of assessments, sample numbering, study sites and patient numbering.
- Database Design Document (DSD): The DSD is an internal pRED document which is created for all studies, and provides a study-specific source document for the validation checks, eCRF behaviours, derivations and source data verification (SDV) for all data collected and derived within a study database.
- "Clarifications" document. This document provided the "missing link" for the testers who had no standards to base their study design on. It consisted of a list of exact requirements for each variable to be built in the test study scenario, grouped by form. Located within this document were the definitions of all variables and forms to be used by the testers in the non-standards test scenarios.
- "Background information document. This document was provided as a source of protocol-specific information (such as safety lab panel), which would not be found within the MDD or DSD.
- "CDP task & time record" document. This document was provided to each tester in order for them to record time spent on a specific set of high-level tasks. An example of this document is shown in Figure 1 below.

Figure 1: CDP task and time record

CDP Name	
Task Description	**Time taken (hours)**
Stage I build – create fields, forms, folders, etc.	
Stage I build – create and test eCRF behaviours	
DSD – create and unit test edit checks/custom functions	
DSD – fix user acceptance fails	

The "Stage I build – create fields, forms, folders, etc." is the first task done when carrying out database setup. It consists of the creation of data collection objects within a study and the corresponding schedule of assessments as defined in a protocol.

The “Stage I build - create and test eCRF behaviours” task would mainly involve programming eCRF triggers and custom functions in order to add forms to specific visits and also to default values such as sample numbers and scheduled times, as well as control visibility of certain variables depending on requirements within each specific visit.

The “DSD – create and unit test edit checks/custom functions” task involves the creation of data validation edit checks and custom functions within a study and the DSD provides the source requirements for this task. It also involves the testing of these edit checks and custom functions and updates to the DSD by the CDP to confirm that each check and custom function listed in the DSD has been built and unit tested.

The “DSD – fix user acceptance fails” task is a post-UAT task, where the CDP would be expected to review UAT fails listed in the DSD, update the database and DSD as required and then confirm that UAT re-testing can be done. This task may undergo several cycles of testing and updates depending on the results of UAT in each review/update cycle.

Each tester was provided with the documentation relevant to their test scenario and asked to set up the study database using the MDD, DSC, clarifications document and background information documents as references. Each tester was asked to record as accurately as possible the time taken to complete certain predefined high-level tasks. These tasks were discussed and agreed by the experimental designers to be the tasks expected to show the benefit of standards within the scope of the experimental design.

Following completion of study setup, all results were sent to the experimental designer by the testers. The results consisted of the CDP task and time record as well the updated DSD for each test scenario.

RESULTS

The results were received from each tester and tabulated (Figure 2).

Figure 2: Time taken (hours) for each task by each tester, by standards level used

Task Description	100% Use of standards	50% Use of standards	No use of standards
Stage I build – create fields, forms, folders, etc	3	5	9
Stage I build – create and test eCRF behaviours	5	5	4.5
DSD – create and unit test edit checks/custom functions	1.5	15	21.5
DSD – fix user acceptance fails	TBD	TBD	TBD
Total	9.5	25	35

Task “Stage I build – create fields, forms, folders, etc.” showed a strong benefit towards use of standards, with a greater benefit shown when compared to the 0% standards test scenario. It was notable that this task was generally not particularly time-intensive but there were still strong efficiency savings to be made. There is a strong indication from the 3 test scenarios that the higher the level of standardization of fields, forms and other basic database objects, the higher the efficiency benefit.

Task “Stage I build – create and test eCRF behaviours” had a broadly similar time spent in each test scenario. This was expected because in the RAVE system it is particularly challenging to standardize this task, due to study-specific objects being required within each of the behavioural custom functions needed (e.g. folders/visits). The small variation within this task may have been due to tester experience level.

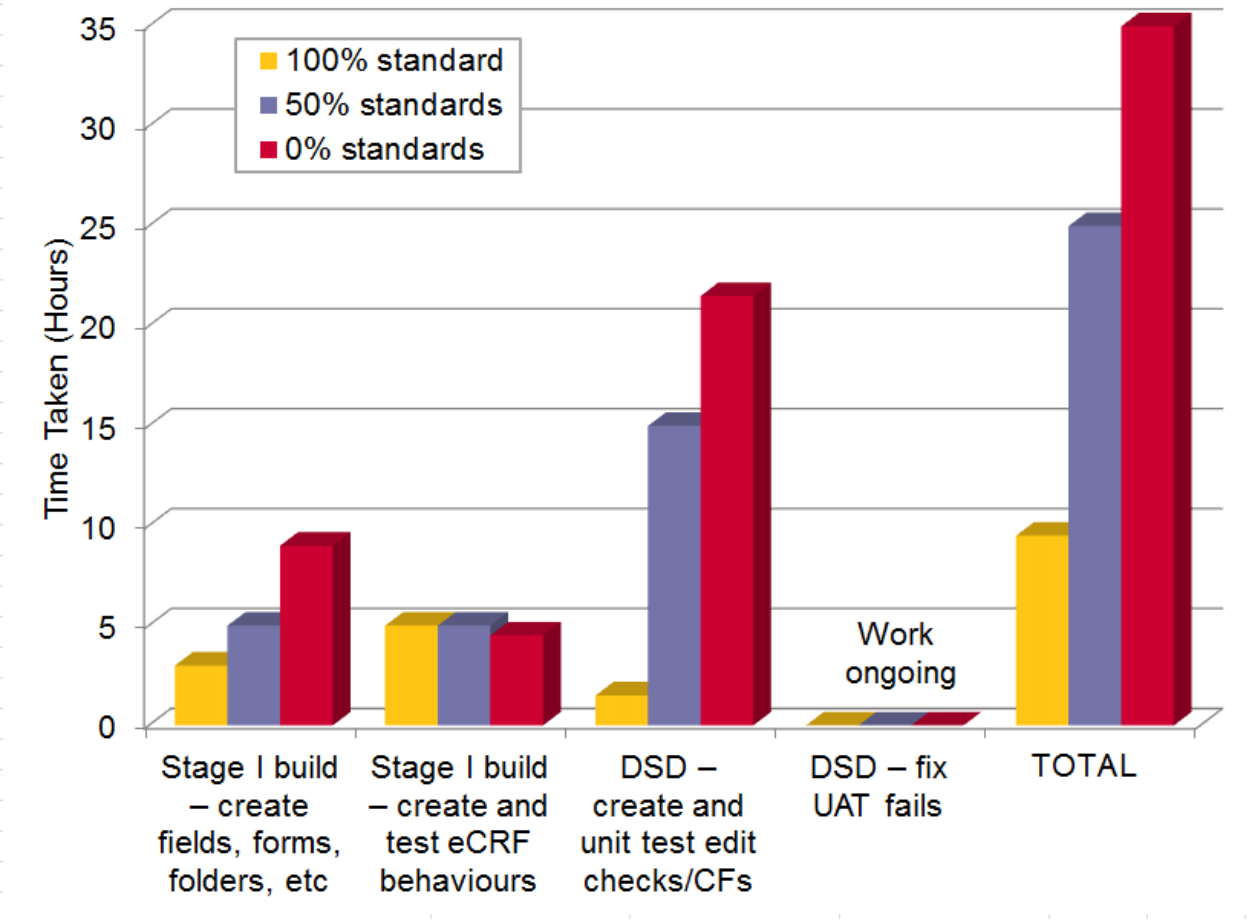
Task “DSD – create and unit test edit checks/CFs” shows a very strong efficiency gain in the 100% standard design when compared to both of the other test scenarios. The extent of the efficiency gain here was perhaps greater than expected and underlines the importance of having a library of standardized validation checks available for use.

Task “DSD fix UAT fails” is currently incomplete due to time constraints, therefore unfortunately cannot be included. It would have been expected that this task would show not only an efficiency gain in time spent, but also an efficiency gain in build quality, in terms of frequency of UAT fails encountered. When we complete this task, we

expect to confirm that greater use of standard validation checks and custom functions show an efficiency benefit both in terms of fewer UAT fails and in less time spent by the testers fixing UAT fails.

The tabulated results in Figure 2 transfer well to a graph format, where the task-specific efficiency gains are very apparent (Figure 3).

Figure 3: Time taken (hours) by task, split by test scenario



By adding the individual high-level tasks, it can be seen that the "TOTAL" in figures 2 and 3 indicates that the 100% standards test scenario has resulted in a study build time of 9.5 hours, compared to 25 hours for the 50% standards test scenario and 35 hours for the no standards test scenario.

Within the scope of this experimental design, this means that the 100% standards test scenario was built in RAVE in 38% of the time taken to build the 50% standards test scenario, and just 27% of the time taken to build the no standards test scenario.

It is also important to note that the 50% standards test scenario was built in approximately 71% of the time taken to build the no standards test scenario, as this 50% standards test scenario may be a more accurate reflection of a "true" study build, which would use both standards and non-standards.

CONCLUSION

There is a clear relationship between efficiency of database setup and use of standards. We propose that the widely-held belief that standardization increases efficiency in database build has been proved. The extent of the efficiency saving within the scope of this experiment was perhaps even greater than expected; therefore it is clear that standards adoption should be a vital consideration for any study management team.

It is important to stress that the test scenarios contain the extremes of standardization and non-standardization. In a real study, it is highly unlikely that 100% of a study could be built using standards only. Equally, it is very unlikely that a study would be built with no use of standards. The test scenario where 50% standardization was used could be considered to be a more realistic representation of a real study design as it contains a mix of standard and non-standard objects. Therefore we would also propose that the greater the standards usage within a study, the greater the benefits to the efficiency of the study build.

The benefits of standardization have been proven within a single role (CDP) and within certain tasks assigned to that role. Further benefits of standardization prior to and after these tasks within the study setup and conduct process would be expected. Tasks outside the scope of this experiment which could also be shown to benefit from standardization would include: Protocol design, MDD design, DSD design, lab admin setup, data cleaning, data extraction including mapping to SDTM format and of course, data visualization and analysis.

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