SCTO PLATFORMS

Clinical Data Management Systems (CDMS) Evaluation Report

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Data Management Platform – Project Report
Clinical Data Management System (CDMS) Evaluation

Version: 09.09.2021, de-identified version (names of newly evaluated CDMS have been removed for publication on the SCTO webpage)

Reporting period: Q1 2018 – Q2 2020

Content

Executive summary

The Clinical Trial Unit (CTU) Network of the SCTO has been working with secuTrial for over a decade and more recently several CTUs have incorporated REDCap into their data management (DM) portfolio. The choice of secuTrial was based on a systematic evaluation of Clinical Data Management Systems (CDMS) which was, however, performed over ten years ago. In light of the ever-increasing speed of developments in digital technology it was considered vital to obtain an up-to-date impression of the currently available options and assess potential alternatives. For this, a compendium of system requirements was constructed and sent to CDMS vendors for consideration. Based on the replies of the software vendors regarding fulfilment of requirements and pricing, the CDMS solutions secuTrial and REDCap remain not only viable, but currently the best options for the CTU Network.

1 Introduction

Clinical Data Managements Systems (CDMS) are a central component of the digital architecture in modern clinical trial and registry databases. They enable implementing custom Clinical Data Management Applications (CDMA) in which study data can be recorded, viewed and from which it can ultimately be exported for downstream analysis tasks. CDMAs are commonly made up of a set of electronic case reports forms (eCRF). A set of eCRFs can then be arranged according to a specified time/visit plan. Data can be entered into eCRFs directly during initial data collection or alternatively data from paper based forms can be transferred to the digital form interface at a later stage. Both the implementation of eCRFs and the entry of data into eCRFs should be as intuitive as possible while enabling workflows adhering to Good Clinical Practice (GCP). A plethora of commercial and non-commercial CDMS suppliers is presently available. An evaluation performed by the CTU Network returned secuTrial[10] as the most favorable candidate for the network's functional and financial requirements. However, the previous evaluation of available software solutions was conducted over ten years ago. Thus, it was concluded that the SCTO's Data Management (DM) Platform[13] should reassess available CDMS solutions. The primary objectives of the evaluation are to place the presently applied systems secuTrial[10] and REDCap[9] in the CDMS landscape and to evaluate potential alternatives both from a functional perspective and from a financial point of view. The results and conclusions of this evaluation are presented in this report.

2 Methods / Project Plan

The plan for the project was to first compile a compendium of priorities for the CTU Network regarding CDMS solutions. Specifically, the plan was to assess which types of CDMS were of interest. This was to be followed up by specifying a list of technical properties which were considered to be important by the DM platform members (i.e., a requirements list). Additionally, the cost of individual CDMS was to be taken into account. Formal replies regarding the fulfilment of the CDMS requirements were to be retrieved from software vendors followed by informal testing of the software solutions performing best in the systematic evaluation. In the following we describe the methods and deviations from this plan if they occurred.

2.1 SCTO DM Platform questionnaire I

In the first stage of the project (Q1 2018) all members of the SCTO DM Platform (several votes per CTU were possible) were encouraged to give feedback on which types of CDMS are currently in use and for which further CDMS an evaluation may be of general interest. A previously performed ECRIN survey on CDMS was used as anchor point[14]. Furthermore, different types of functionalities were grouped into classes (e.g., monitoring, reporting, eCRF creation, data entry) and the participants in the network were asked to assign importance to the classes.

2.2 Requirements engineering

In order to allow a systematic analysis of the availability of functionalities per CDMS, it is central to first specify the functionalities in a structured manner. This process of defining and structuring the required functionalities of a system

is referred to as requirement engineering. Based on the regulatory framework arising from the Human Research Act, General Data Protection Regulation (GDPR), GCP guidelines, the United States Food and Drug Administration (FDA), Swiss legal and regulatory requirements, and CTU internal business processes, an initial draft for a requirements catalogue was created at CTU Bern. The requirements revolve around five central topics.

- Supplier profile requirements (SPR) which are related to certifications and experience the supplier should have.
- General functional requirements (GFR) which describe the expected functionalities the software should include. i.e., “What” tasks can the software perform?
- Non-functional requirements (NFR) which describe how the software operates. i.e., “How” does the software perform its tasks?
- Process-specific requirements (PPP) which describe the expected functionalities related to CTU-specific business processes and workflows (i.e., data entry, monitoring, data management, statistics).
- Regulatory requirements (REG) which describe what must be fulfilled in order to comply with applicable FDA and EU regulations and adhere to best practices and guidelines.

In the next step the DM, quality management, central and onsite monitoring, clinical investigation and statistics divisions of the CTU Bern reviewed the drafted requirements. The catalogue was subsequently updated based on the feedback in the review. The catalogue was then distributed to all members of the DM Platform for a further review cycle. Specifically, the importance of each requirement had to be judged on a three tiered scale from “must have” over “nice to have” to “not required”. Furthermore, tangibility and completeness of the list was evaluated. One consolidated vote per CTU was considered. The consolidation of importance-votes per CTU was performed by applying the mode averaging method. Based on this feedback, the list was finalized by adding missing requirements, merging/deleting redundant items and adding the consolidated judgment related to the importance of the requirements. The content of the final list as well as the importance of every requirement (see Appendix 8.6) was approved during the DM Platform meeting on the 6th of June 2019.

2.3 Extension of systems to evaluate

Due to requests from within the DM Platform, the list of systems to evaluate was extended by a system under development at the Ospedale Regionale di Lugano and two additional commercial system even though they were not considered in the SCTO DM Platform questionnaire I.

2.4 Commercial vendor contacting

Several members of the DM Platform reached out to the vendors of eight different systems. For confidentiality reasons, they will be referenced in this report as CDMS1, CDMS2, CDMS3, etc. All vendors except for those of secuTrial were contacted based on the same contact template (see Appendix 8.3) to maintain consistency in the preliminary interaction.

secuTrial was contacted with a slight variation of

the template and in German language because the impersonal generic template was not deemed appropriate in this case (see Appendix 8.4). The vendors were asked to supply feedback on each requirement and report on whether the requirement is met directly, indirectly or not at all. Furthermore, the DM Platform inquired regarding sales and pricing models of the individual solutions.

2.5 Cost neutral vendor evaluation

REDCap was evaluated by the DM staff of CTU Bern and not by the REDCap developers.

2.6 SCTO DM Platform questionnaire II

The results (lack of fulfilled requirements, excessive costs, impracticable pricing model) from the analysis of the feedback from the software vendors sparked the question whether the originally envisioned project plan (i.e., systematic informal testing of promising CDMS solutions) was still the most suitable track or whether a deviation was in order. Thus, a second questionnaire to the SCTO DM platform members was prepared asking for opinions and possible future directions. Specifically, the platform members were asked whether the project should be shortened in favor of a track on which only the CDMS13 will be more closely examined. Furthermore, since the results of the vendor feedback (see Section 3.5) indicate that secuTrial remains the correct CDMS for the CTU Network, the question was raised how to proceed regarding future use and extension of secuTrial. Thus, the DM network was asked to give feedback on the idea of implementing central secuTrial instances to reduce IT maintenance cost. Also, since there are ongoing performance issues and feature requests, the idea of investing into a full programmer position to add extensions and repairs to secuTrial was queried. There was one vote per CTU.

2.7 Questionnaire implementation

The questionnaires to the DM Platform members were implemented in REDCap[9].

2.8 Data analysis and plotting

Data analysis was conducted in R statistics[15]. Figure plotting was performed under application of ggplot2[16] in R.

3 Results

3.1 SCTO DM Platform questionnaire I

Twenty-four individuals from the SCTO DM Platform filled the questionnaire. Importantly, there was feedback from most institutions (n=8) (see Figure 1). As expected, the questionnaire showed that all institutions in the SCTO DM Platform employ secuTrial as CDMS, while some of the

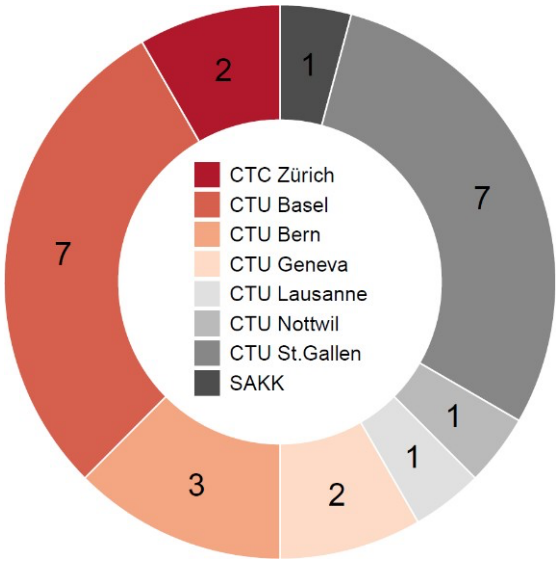


Figure 1: Amount of participants in questionnaire I by institution.

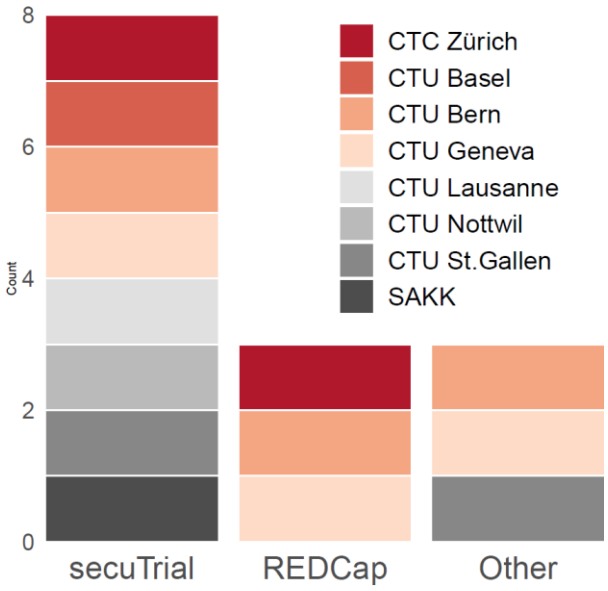


Figure 2: Types of CDMS used by different institutions in the SCTO network. If several participants from the same institution indicated one of the CDMS this was summed to one vote.

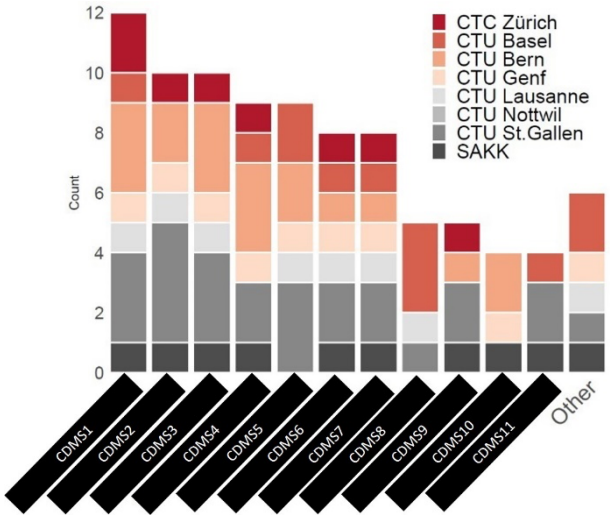


Figure 3: Total votes per CDMS and institution for interest in further evaluation.

CTUs also use other alternatives[9, 11] (see Figure 2). Since the questionnaire the CTU Lausanne has also started working with REDCap. The question on which alternatives to secuTrial may be interesting yielded general interest in a majority of the suggested options. It was thus decided to further follow up on systems for which interest was voiced by at least six institutions (see Figure 3). This yielded CDMS1, CDMS2, CDMS3, CDMS4, CDMS6 and CDMS7. As indicated in the methods section of the report, the list was later extended by the CDMS5, CDMS12 and CDMS13.

3.2 Requirements catalogue

The final catalogue is made up of a total of 162 requirements (see Appendix 8.6). The total number of requirements is divided into 145 “must have” items and 17 “nice to have” items. Furthermore, the items were subdivided into functional categories which indicate a clear trend towards regulatory requirements, non-functional requirements and data management requirements (see Figure 4).

3.3 Commercial vendor contacting

The majority of vendors replied to the initial contact and were willing to fill the requirements catalogue. The vendors of secuTrial replied within one business day while all other vendors replied with significant delay. The shortest response time of the non-secuTrial vendors was 24 days and the longest was 47 days. The vendors of CDMS5, CDMS6 and CDMS7 did not reply to the initial contact and were not followed up. The interaction with all vendors who replied was evaluated as positive and appropriately professional.

3.4 Commercial license costs

The pricing models of the different CDMS vendors (see Appendix 8.5) generally show a trend towards licensing by a rigid "Study-by-Study" (SBS) model or by a "Software as a Service" (SaaS) model in which fees are invoiced per named user, database or even per data point in a CDMA. Fees for enterprise models (i.e., flexible flat rate licensing) were not disclosed or enterprise models were not available. For confidentiality reasons, we will not disclose any pricing information, but it can be stated that the majority of CDMS solutions have an associated cost which is far beyond the financial scope of the CTU Network's academic setting.

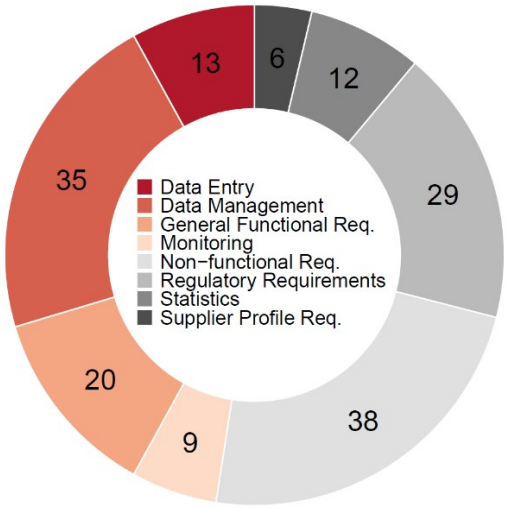


Figure 4: Amount and types of requirements in the catalogue.

3.5 Vendor feedback on the requirements

The performance regarding the "must have" requirements was generally good throughout all CDMS considered with the CDMS3, CDMS4, CDMS13 and secuTrial exhibiting the best numerical performance.

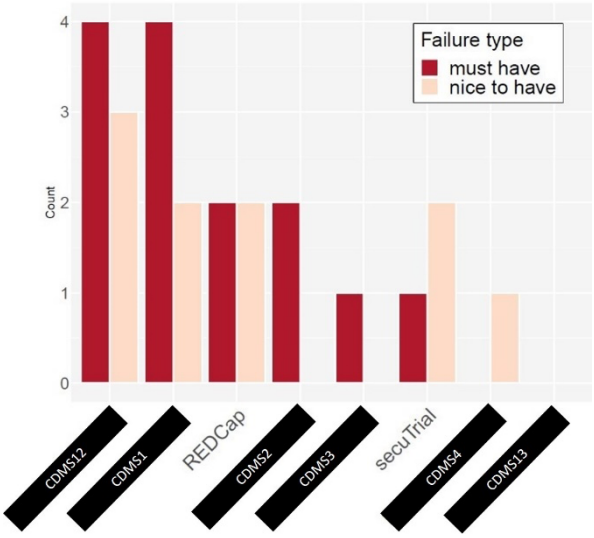


Figure 5: Amount of failed "must have" and "nice to have" requirements per CDMS.

The requirements classified as "nice to have" showed similar performance. Of note, the CDMS13 has no failed "must have" and no failed "nice to have" requirements (see Figure 5).

3.6 SCTO DM network questionnaire II

Given the results of the requirements evaluation, the option to shorten the project in favor of a deeper dive into the CDMS13 was elected by over 85% of the departments participating in the questionnaire (see Figure 6). The same majority voted to investigate the option of allocating more resources towards the future development of secuTrial (see Figure 6). Regarding the approach of hosting central and shared secuTrial instances the network is more undecided with a small majority being in favor of at least looking into this option (see Figure 6).

Figure 6: Choices per question in questionnaire II.

4 Discussion

The evaluation of CDMS solutions started with the clear expectation that it would yield alternatives which significantly outperform secuTrial and REDCap. Interestingly, the results indicate that while there are many solutions on the market none of the commercial vendors, who consider the SCTO a big enough customer, outclass secuTrial or REDCap to a degree which warrants the extensive overhead of planning a CTU Network wide change of the setup. Importantly, most vendors fail to be an alternative due to lacking the option of an enterprise cost model which allows the flexibility the CTU Network requires. Thus, even without regarding the fulfilment of system requirements, the majority of CDMS solutions is already invalidated due to the associated cost overhead/pricing model (see Appendix 8.5 – due to confidentiality reasons, detailed pricing information has been removed). The only CDMS including an enterprise model is CDMS2 (see Appendix 8.5) which, however, fails to fulfill the crucial requirement of allowing a local installation of the software (see Appendix 8.6, NFR.007).

The secuTrial vendors state that they do not fulfill the business continuity requirement (see Appendix 8.6, REG.016) but also correctly point out that the responsibility lies with the party hosting the secuTrial instances, which are in this case the CTUs themselves. Furthermore, study setups cannot be achieved by importing definitions that were defined outside of secuTrial (see Appendix 8.6, PPP.002) and no training videos are available for (see Appendix 8.6, NFR.035). The latter can likely be set up by the DM Platform through an extension of the already ongoing secuTrial recipes efforts[17]. Thus, in contrast to the initial notions within the DM Platform, the evaluation of CDMS solutions yielded the clear insight that there is no commercial alternative to secuTrial which is both functionally superior and financially feasible at this point in time.

While the commercial solutions investigated in this evaluation may not represent alternatives to secuTrial, the non-commercial solutions REDCap and CDMS13 may be cost efficient options to further keep in mind. As previously shown (see Figure 2) some CTUs have already been actively using REDCap. Importantly, however, REDCap fails or only partially fulfils certain requirements. For instance, while external randomization lists can be uploaded, there is no module to generate randomization within REDCap (see Appendix 8.6, PPP.051) and a separation of the setup and productive environment can only be achieved with a workaround (see Appendix 8.6, PPP.022). Having said that, it should also be stated that the evaluation of REDCap was no self-assessment by its developers/suppliers and thus likely stricter.

Thus, REDCap remains an alternative to secuTrial which is cost neutral and suited for less complex clinical trial setups or "do-it-yourself" approaches for clinical researchers working with the CTUs. In summary, secuTrial and REDCap are the best suited CDMS options for the SCTO's CTU network in the current situation. Other cost effective systems may also be evaluated in future if they become available.

4.1 secuTrial versus REDCap: when to use which system?

In terms of provided functionalities, REDCap has difficulties to fulfil the following requirements when configuring a study database:

- Blinded study; it is not possible to define a study as "blinded".
- Repetitions/sub-entities; it is not possible to have sections repeated within a form. However, it is possible to repeat complete instruments or visits.
- Form completion status; the status needs to be set manually to "unverified" or "complete".
- Creation of reports; only very basic reports can be configured in REDCap.
- Separate development and production environment is not available in REDCap.

If these requirements arise for the setup of a given study database, which is likely for more complex trials and trial designs, we recommend using secuTrial instead of REDCap. However, if a trial or study intends to employ online surveys, we strongly recommend the usage of REDCap at least for the survey part of the data collection. Furthermore, if the investigators intend to set up study databases on their own, then REDCap is also the recommended solution since – in comparison to secuTrial – it is more user-friendly and intuitive to use. In conclusion, REDCap is a strong system with many advantages, mainly in academic research. However, it can not be used as the only CDMS at CTUs because it does not cover all requirements of complex clinical trials.

5 Outlook and next steps

Even though secuTrial may have performed well in this evaluation it is not free of challenges both for data managers implementing CDMAs and for data entry personnel. When queried about ongoing challenges, secuTrial users from the DM Platform will frequently indicate issues with the general usability of the tool (especially for beginners) and the accessibility of data within. Thus, a closer collaboration with the vendors of secuTrial is envisioned through which the status quo of the software can be likely further improved. More recently, the secuTrialR[18] software package has been developed in a shared effort of CTU Basel and CTU Bern. secuTrialR can be used as an application programming interface (API) to interact with secuTrial databases close to real time since recent updates to secuTrial itself now allow data to be automatically uploaded to a secure and accessible file server on a 24 hour basis. With the help of the secuTrialR package it will be possible to solve issues regarding datareporting and display more easily and independently of the secuTrial vendors thusimproving the overall experience of working in a secuTrial dependent environment. A pilot project using the R Shiny framework[19] is already ongoing[20] and is a well suited candidate for strong support in the funding period 2021-2024.

5.1 CDMS13 follow up

After a demo presentation (23rd of April 2020) of the CDMS13, the members of DM Platform agree that this system requires additional maturation cycles before it can be considered as an alternative to secuTrial.

In the present state the application is not able to replace secuTrial or REDCap, nor can it provide added value for specific study setups.

5.2 secuTrial service continuity

The secuTrial application is currently based on the application framework «WebObjects» originally developed by NeXT Software in 1996. Since 2009 the framework is maintained by an independent volunteer community. This raises the question of related risks to service continuity for the browser based secuTrial software.

WebObjects is primarily a java based web- and application server, comparable to PHP or ASP.NET. The secuTrial application is thereby provided to users in the form of websites using common html5, javascript and css technology. Importantly, given that browser vendors rarely remove support for existing features, there is a low probability, that currently working releases of secuTrial will not work in new browser releases.

If problems should arise in new browser releases, fixing the respective issues should be possible with minor effort, due to the modular separation of logic and user-interface components built into the WebObjects framework. However, this depends on the source code and WebObjects developer tools being available and working and the willingness of the vendor to fix respective issues.

Strict configuration management should be used to deploy host systems running the secuTrial server application, since updates to operating system components or the java runtime might be incompatible with the WebObjects framework. Virtual machine images or docker images might be used to allow quick re-deployment and testing of new secuTrial or operating system releases.

For long term sustainability a re-implementation of secuTrial using newer frameworks and solutions or transitioning to a different CDMS might alleviate some concerns. However, currently employed standards can also be discontinued.

6 Acknowledgements

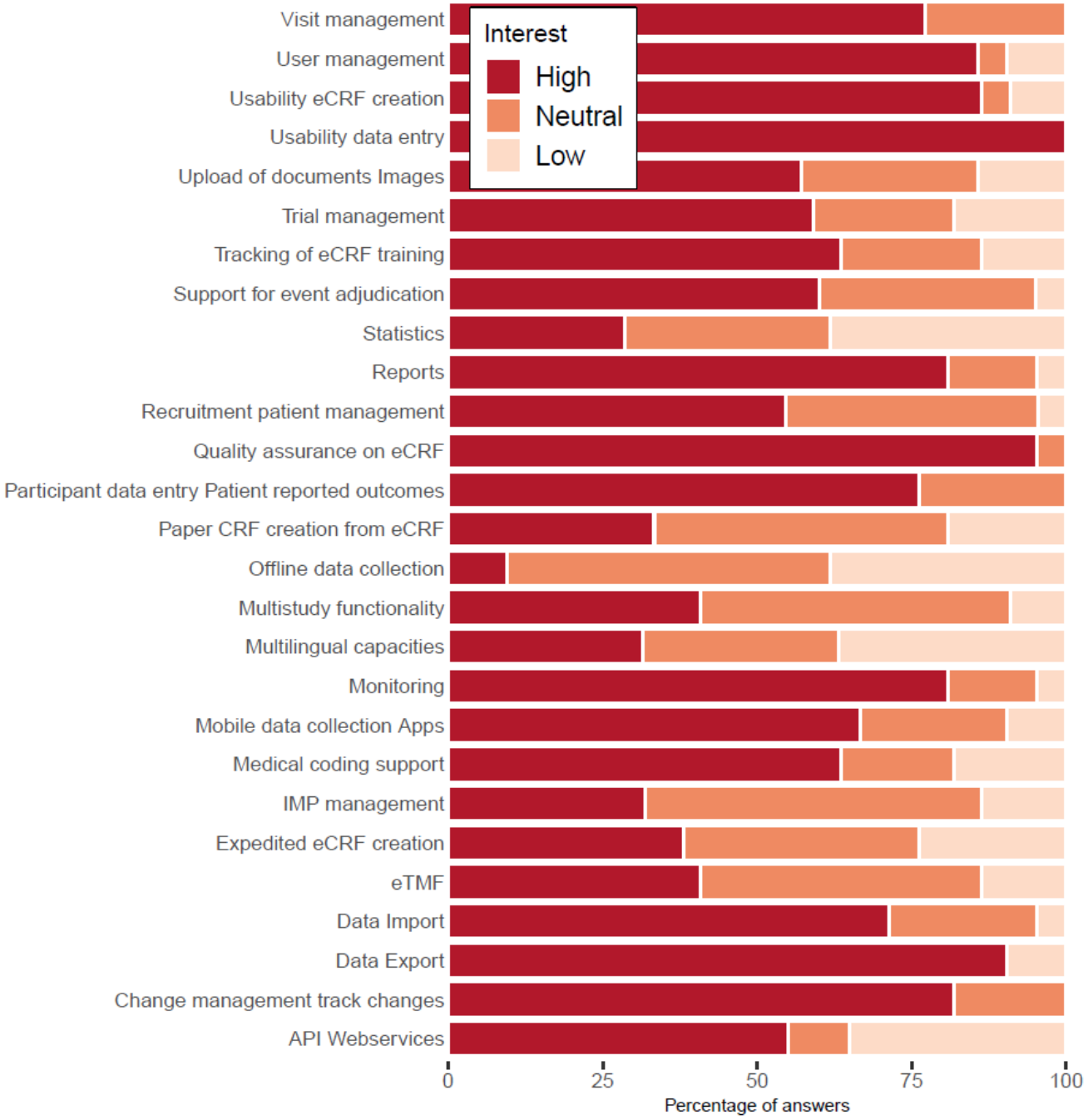
The authors thank the State Secretariat for Education, Research and Innovation and the Swiss National Science Foundation for the funding of this project. Furthermore, the authors express their gratitude to all members of the SCTO and SCTO DM Platform for their active and ongoing participation.

7 References

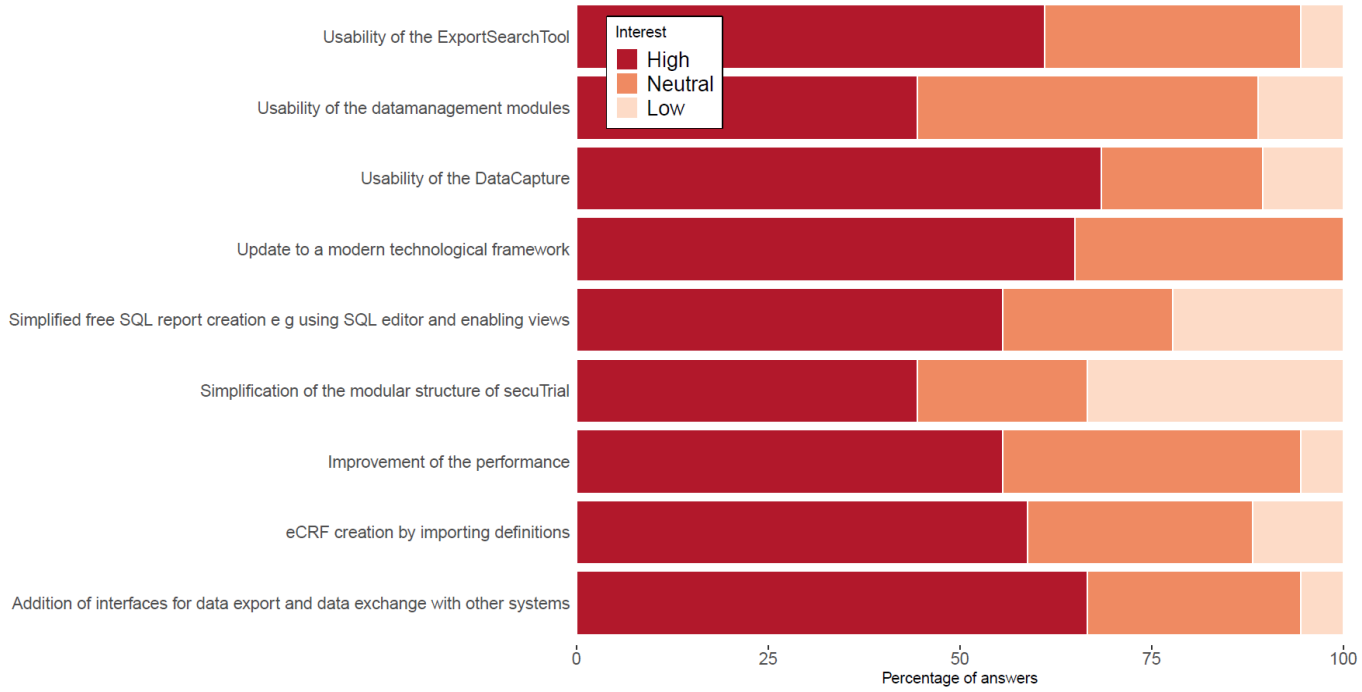
1. weblink vendor website CDMS1
2. weblink vendor website CDMS4
3. weblink vendor website CDMS7
4. weblink vendor website CDMS2
5. weblink vendor website CDMS5
6. weblink vendor website CDMS6
7. weblink vendor website CDMS3
8. weblink vendor website CDMS12
9. https://www.project-redcap.org
10. https://www.secutrial.com/
11. weblink vendor website CDMS10
12. weblink vendor website CDMS9
13. https://www.sctoplatforms.ch/
14. https://www.ncbi.nlm.nih.gov/pubmed/20663165
15. https://www.r-project.org/
16. https://ggplot2.tidyverse.org
17. https://swissclinicaltrialorganisation.github.io/secuTrial_recipes/
18. https://github.com/SwissClinicalTrialOrganisation/secuTrialR
19. https://shiny.rstudio.com/
20. https://github.com/SwissClinicalTrialOrganisation/secuTrialRshiny

8 Appendix

8.1 How important are the following CDMS functionalities to you?



8.2 With regard to secuTrial, how important are the



8.3 Vendor contact email template

Dear [insert name of contact at vendor],

The Swiss Clinical Trial Organisation is currently evaluating several Clinical Data Management Systems (CDMS).

We would like to invite you to give us feedback on your CDMS solution and its functionalities by filling in the tabs “general information” and “functionalities” (column D) of the attached Excel file “CDMS supplier feedback list”. If you partially fulfil a given functionality, please comment on how your tool provides (parts) of the described functionality.

We would appreciate receiving the completed “CDMS supplier feedback list” by the 16th of August 2019.

Since we are performing an objective comparison of CDMS software, we need your formal feedback before any in person presentation or demonstration of your tool can take place. The completed requirements list willserve as basis for further consideration.

Should you have any questions, please do not hesitate to

contact me. Best wishes, [insert name of DM Platform

member performing contact]

In attachment you can find the Excel file “CDMS_Supplier Feedback_List.xlsx”, referenced in the text above.

8.4 secuTrial contact email

Liebe [insert contact person for secuTrial],

im Rahmen eines Projekts der SCTO evaluieren wir aktuell verschiedene CDMS-Lösungen. Selbstverständlich spielt secuTrial in dieser Evaluation eine zentrale Rolle. Es geht uns unter anderem darum, unseren Kunden eine gute Antwort geben zu können, wenn sie uns fragen, warum wir Lösungen mit secuTrial anbieten.

Um eine systematische Evaluation durchführen zu können, haben wir einen Katalog mit Funktionalitäten ausgearbeitet (siehe Anhang). Ausgefüllt werden sollte vornehmlich Spalte D. Falls D nur teilweise zutrifft, dann kann in Spalte E kommentiert werden.

Wäre es möglich, wenn Sie oder einer Ihrer Mitarbeiter diesen Informationsbogen bezüglich secuTrial bis Mitte/Ende August ausfüllt?

Vielen Dank und beste Grüsse aus Basel.

8.5 Pricing models

SaaS = Software as a Service; SBS = Study by Study; GPL = General Public License

CDMS	Licence Model
CDMS1	• Monthly SaaS fee per named user
CDMS4	• Monthly SaaS fee per named user
CDMS2	• Not assessed, since the must-have requirement NFR.007 is not fulfilled
CDMS12	• SBS
CDMS3	• SBS
CDMS13	• GNU GPL 3
REDCap	• Free for non-commercial research purposes
secuTrial	• Depend on hosting, number of installations and projects if hosted by iAS

8.6 Requirements catalogue

Importance: 1 = nice to have; 2 = must have

Code	Title	Description	Category	Importance
GFR.001	**ONE PLATFORM**	The System shall have the ability to manage all databases in a single platform.	General Functional Requirements	**2**
GFR.002	**INTEGRATED SYSTEM**	The System shall supply its tools and functionalities (e.g. CDMS, KPIs, surveys etc.) within one single system.	General Functional Requirements	**1**
GFR.003	**PROCESS WORKFLOWS**	The System shall have the ability to manage and configure/parametrize each particular research database individually and will follow the workflow pre-defined for that database.	General Functional Requirements	**2**
GFR.004	**PATIENT RECORD IDENTIFICATION**	The System shall assign a unique identifier to each patient within a project.	General Functional Requirements	**2**
GFR.005	**ORGANISATIONAL SCOPE**	The System shall ensure that every research database is uniquely attributable to a single study (=clinical research project)	General Functional Requirements	**2**
GFR.006	**STATUS MANAGEMENT**	The System shall ensure that edited forms are status tracked (e.g. incomplete; partially complete; done; reviewed).	General Functional Requirements	**2**
GFR.007	**USER PERMISSIONS**	The System shall manage the user access level to perform activities (e.g. form data manipulation [i.e. create, read, update, delete], export, monitoring activities [e.g. queries, source data verification, review, etc.) depending on his/her authorizations (= rights), which will be determined by the following combined criteria: - Roles can be generated and assigned to a user. Users can only have one role per study center. - User authorization (granted by role assignment) to perform the activities depending on the user requirements.	General Functional Requirements	**2**
GFR.008	**VISIT PLAN**	The system shall allow that a visit plan can be specified for each study. The system allows the handling of different study arms.	General Functional Requirements	**2**
GFR.009	**DUE DATES**	The system shall allow defining due dates based on the visit plan.	General Functional Requirements	**2**
GFR.010	**DUE DATES OVERVIEW**	The system shall provide an overview of due dates which be extracted and/or for which reminders can be defined.	General Functional Requirements	**1**

GFR.011	**DEPENDENCIES BETWEEN DATA FIELDS**	The System shall have the ability to establish dependencies of a data field on other data fields. Examples: - A data field is mandatory depending on the value of other data fields. - A data field can only accept some values depending on the value of other data fields.	General Functional Requirements	**2**
GFR.012	**SUPPORTED DATA TYPES**	The System shall support (but not be limited to) the following data types: numeric values, date / time, short text, long text, etc.	General Functional Requirements	**2**
GFR.013	**UPLOADS / REPOSTIORY**	The System shall have the ability to attach files of any format (non-exhaustive list includes txt, eml, docx, xlsx, pptx, pdf, jpeg, tiff, mpeg, zip, rar...) and to a study site, record or a CRF.	General Functional Requirements	**2**
GFR.014	**AUDIT TRAIL**	The System shall keep track of all auditable events on the CRF through an audit trail. An audit trail should be kept for all changes to the system's configuration.	General Functional Requirements	**2**
GFR.015	**AUTOMATIC EMAILS**	The System shall have the ability to automatically send email messages to concerned users in order to notify them of certain events or remind them of tasks according to pre-defined rules.	General Functional Requirements	**2**
GFR.016	**DATA CONCURRENCY**	The System shall allow multiple end-users to access the same DB simultaneously while being able to maintain data integrity and database consistency. In particular, the System shall ensure that multiple users can view the same DB but only one can change it at a point in time on one single form.	General Functional Requirements	**2**
GFR.017	**DATA CHECKS**	The System shall check data for consistency after data entry in case of invalid or missing data and inform the user through pre-defined error messages.	General Functional Requirements	**2**
GFR.018	**STUDY SETUP BY CTU**	The system shall allow the use of all funtionalities as well as the creation and setup of new studies by CTU without the assistance of the supplier.	General Functional Requirements	**2**

GFR.019	**DIFFERENT VISIT TYPES**	The system shall allow that visits can be defined as fix (specified sequence) or unscheduled (can be added / created at any time during the course of the study).	General Functional Requirements	**2**
GFR.020	**GUI ELEMENTS**	The CDMS shall support (but not be limited to) the following selectors: radio buttons, checkboxes, drop downs, calendar, catalogues, etc.	General Functional Requirements	**2**
NFR.001	**USER MANAGEMENT ADMINITSTRATOR**	The System shall provide the option to only allow administrators of the CTU to assign authorizations to users.	Non-functional Requirements	**2**
NFR.002	**PASSWORD MANAGEMENT**	The system shall ensure that the password management respects the following points: · Strong password policy · Password expiration policy · Password reset functionality	Non-functional Requirements	**2**
NFR.003	**WEB BASED SYSTEM**	The system shall be web based, running on all common web browsers (also older versions).	Non-functional Requirements	**2**
NFR.004	**MOBILE DEVICES**	The CDMS shall be accessible through mobile devices (iOS, Android, Windows Phone / Mobile). Simple actions can be executed from devices.	Non-functional Requirements	**2**
NFR.005	**RESPONSIVE DESIGN**	The system shall ensure that the GUI is optimized to the respective screen size of the device the web application is used on.	Non-functional Requirements	**2**
NFR.006	**SCALABILITY**	The System shall allow to expand its capacity by adding hardware resources (without need for software changes) and support increases in the number of users, data volume, and intensity of use while ensuring continuous fulfilment of all requirements.	Non-functional Requirements	**2**
NFR.007	**LOCAL INSTALLATION / HOSTING**	It shall be possible to install and host the system locally at our institution.	Non-functional Requirements	**2**
NFR.008	**BUG REPORTING AND FIXING**	The supplier provides an overview of all reported bugs and fixes critical bugs within 10 days.	Non-functional Requirements	**2**
NFR.009	**SUPPORT HOURS**	The Supplier technical support hours should be as follows: - 8-9 hours a day from Monday to Friday, if the System is fully built on CTU infrastructure (On-Premise)	Non-functional Requirements	**2**
NFR.010	**SOFTWARE MAINTENANCE**	The Supplier shall provide CTU with at least 1 major software release per year at least 3 minor release per year.	Non-functional Requirements	**2**

NFR.011	**RELEASE ROADMAP**	The Supplier shall provide CTU on a yearly basis with an overview of planned enhancements and new features of its products and services.	Non-functional Requirements	**1**
NFR.012	**LIFECYCLE OF THE APPLICATION**	The Supplier shall ensure to have a system in place to inform customers about development strategy, product discontinuation, etc.	Non-functional Requirements	**2**
NFR.013	**DATA BACKUP & RESTORE**	The System shall generate on a daily basis a backup of the study data and allow to restore the data (on project level, i.e. a single research data base). The backups shall be stored for a week and data restore to any of these backuped states is possible.	Non-functional Requirements	**2**
NFR.014	**DATA ARCHIVING**	The System shall allow to archive a complete study / research data base. Archiving should be possible with data export (in CDISC, PDFs of patient files, etc.). Physical deletion of a productive database shall only be possible after complete archiving of the study. An archived study can be completely restored using the generated archive file.	Non-functional Requirements	**2**
NFR.015	**DATA ENTRY AND REPORTS PERFORMANCE**	Data entry screens and reports shall be swift to load (Test with 3000 patients) and complete in < 2 Min, also with complex queries / SQL statements.	Non-functional Requirements	**2**
NFR.016	**DATABASE CONFIGURABILITY**	The System shall have the ability to create and modify research databases as per study specific requirements. The number of study databases will not be limited.	Non-functional Requirements	**2**
NFR.017	**DATA FIELDS CONFIGURABILITY**	The System shall have the ability to create and modify data fields of any formats as per study requirements. The number of data fields will not be limited.	Non-functional Requirements	**2**

NFR.018	**ELECTRONIC FORMS CONFIGURABILITY**	The System shall have the ability to create and modify the electronic forms for study data entry as per study requirements. It shall be possible to structure each electronic form by adding / removing user-input elements (fields, radio buttons, check lists, long texts, matrix of items, etc.). The number of electronic forms will not be limited. The number of elements in an electronic form will not be limited.	Non-functional Requirements	**2**
NFR.019	**VISIT CONFIGURABILITY**	The System shall have the ability to create and modify repeating visits as well as unscheduled visits	Non-functional Requirements	**2**
NFR.020	**GUI CONFIGURABILITY**	The System shall have the ability to configure GUI elements, including logos, screen titles, and messages, as per CTU and study specific requirements.	Non-functional Requirements	**1**
NFR.021	**AUTOMATIC E-MAILS CONFIGURABILITY**	The System shall have the ability to create and modify (e.g. e-mail messages should have customizable contents including: the study ID, a pre-defined text, the option to add relevant information in the subject of the e-mail, a link to the concerned data field, the possibility to add attachments, etc.) automatic email notifications and reminders as per study requirements (e.g. upon creation or randomization of a patient or a given value for a certain item, emergency unblinding, etc.). The number of email notifications and reminders will not be limited.	Non-functional Requirements	**2**
NFR.022	**EASE OF UPGRADE/UPDATE**	The System shall ensure that the upgrade/update to newer product versions can be completed in a secure and reliable manner, with minimal effort and with support from the supplier if needed (e.g. by providing an upgrade/update script).	Non-functional Requirements	**2**
NFR.023	**CLEAR PURPOSE**	The system's functions shall be easy to use and understand.	Non-functional Requirements	**2**
NFR.024	**ROLE- AND WORKFLOW-DRIVEN ADAPTATION**	The System shall optimize the GUI by enabling / disabling its elements according to the end-user authorizations on the database requirements	Non-functional Requirements	**2**

NFR.025	**USER PREFERENCES**	The System shall allow the user to adjust GUI layout and functions (e.g. language settings, preferred reports, etc.) to suite personal preference and store these adjustments for subsequent sessions.	Non-functional Requirements	**1**
NFR.026	**ONLINE HELP**	The System shall provide self contained and holistic online help	Non-functional Requirements	**2**
NFR.027	**LEARNABILITY**	Processes and functionality shall be easy to learn and remember. After a short training, the end-users shall be able to complete all the activities under their responsibility with minimal need of support.	Non-functional Requirements	**2**
NFR.028	**USEFUL ERROR MESSAGES**	The System shall provide error messages for validation, verification, or run-time problems. The error messages shall be useful and indicate how to resolve the problem.	Non-functional Requirements	**2**
NFR.029	**LOOK & FEEL**	The System shall provide an attractive layout and color scheme, which make the screens pleasurable to look at.	Non-functional Requirements	**2**
NFR.030	**CHARACTER SETS**	The System shall use character sets which cover all the languages for which data will be gathered and stored (e.g. Unicode).	Non-functional Requirements	**2**
NFR.031	**SYSTEM LANGUAGE**	The System's GUI shall be available in the following language: - English	Non-functional Requirements	**2**
NFR.032	**ADITTIONAL SYSTEM LANGUAGES**	The System's GUI shall be available in the following languages: - German - French	Non-functional Requirements	**1**
NFR.033	**DATE & TIME FORMATS**	The System shall enable the use of different date and time formats.	Non-functional Requirements	**1**
NFR.034	**DOCUMENTATION**	The Supplier shall provide documentation in English for training of end-users and System administrators.	Non-functional Requirements	**2**
NFR.035	**VIDEO TUTORIALS**	The Supplier shall provide video tutorials.	Non-functional Requirements	**1**
NFR.036	**TRAINING**	The Supplier shall train CTU personnel on System Administration and end-user functionality.	Non-functional Requirements	**2**
NFR.037	**SUPPLIER AUDITABILITY**	The Supplier agrees to be audited by CTU throughout the lifecycle of the software products and / or services provided.	Non-functional Requirements	**2**

NFR.038	**NOTIFICATION OF ACTIVE USERS**	Administrators of the CTU can send notifications to (selected) users, e.g. to inform them about downtimes due to updates / maintenance etc.	Non-functional Requirements	**2**
PPP.001	**MULTICENTER CAPABILITY**	The system shall support the implementation of multicenter studies (i.e. data entry only sees local data, PI sees all data of the study, access data of parts of centers, manage multicentric patient)	Data Management	**2**
PPP.002	**STUDY SETUP BY IMPORTING DB DEFINITIONS**	The system shall allow to create an eCRF by importing database definitions defined in a structured and machine readable codebook (Excel).	Data Management	**1**
PPP.003	**STUDY SETUP BY PI**	The system shall enable the setup by PIs without the assistance of CTU or the supplier.	Data Management	**1**
PPP.004	**BLINDING OF THE STUDY**	The system shall allow for blinding of the whole study.	Data Management	**2**
PPP.005	**EMERGENCY UNBLINDING**	The System shall allow for emergency unblinding.	Data Management	**1**
PPP.006	**CLASSIFICATION CODES**	The system shall support the addition of classification codes (e.g. ICD-10, ATC etc.).	Data Management	**2**
PPP.007	**COPY-PASTE**	The system shall enable the copying of entire implementations from an existing study database into a new study database.	Data Management	**2**
PPP.008	**COPY-PASTE**	The system shall enable the copying of partial elements such as items and forms within a study, including the validation and defined rules.	Data Management	**2**
PPP.009	**DATA VALIDATION**	The system shall offer a function to define the validation of data fields in order to ensure that entered data complies with a given format (e.g. such as date DD/MM/YYY, number, letters only etc.)	Data Management	**2**
PPP.010	**DATA VALIDATION PLAN**	The system shall support the creation of a data validation plan (containing all edit-checks to be performed on the collected data) within the system. The system shall enable the verification of the defined data validation plan.	Data Management	**1**
PPP.011	**PLAUSIBILTY CHECKS**	The system shall have the ability to perform plausibility checks (i.e. cross-checks between data entry fields in order to avoid obvious contradictions).	Data Management	**2**

PPP.012	**PLAUSIBILITY / EDIT CHECKS**	The system shall support the definition of edit checks which can be defined for data entry fields (i.e. the system allows the definition of mandatory fields, range checks, cross field/forms check, complex consistency checks, etc.)	Data Management	**2**
PPP.013	**SAVING OF ERRONEOUS eCRF**	The system shall have two levels of plausibility checks: Strong (error) and soft checks (warning).	Data Management	**2**
PPP.014	**ADAPTATION OF PRODUCTIVE STUDIES**	The system shall support the addition of new eCRFs in productive studies. The system shall support the addition, hiding or disabling of individual fields to an eCRF in productive studies. The system shall support the modification of the visit plan during production.	Data Management	**2**
PPP.015	**ADAPTATION OF PRODUCTIVE STUDIES**	The system shall support the adaptation of productive studies. The system shall indicate if a change to the database leads to an inconsistency or loss of data.	Data Management	**2**
PPP.016	**ADAPTATION OF PRODUCTIVE STUDIES**	The system shall support in detecting risky changes (i.e. changes that lead to inconsistent data or to a corruption of the integrity of the database) in productive studies. The System informs the user if data would be changed or deleted before saving such a risky change.	Data Management	**1**
PPP.017	**TRACEABILITY**	All modifications of the eCRF shall be traceable.	Data Management	**2**
PPP.018	**IDENTIFYING DATA**	The system shall provide the option to mark identifying variables	Data Management	**2**
PPP.019	**DATA VALIDATION**	The system shall offer the possibility to re-run the data validation rules for all patients after changes have been done to the eCRF. The system informs the user about the consequences of this revalidation of validation rules before saving the changes to the database.	Data Management	**2**
PPP.020	**FREEZING**	The system shall support the freezing/locking of individual forms in the database upon completed data entry (via admin login; performed manually).	Data Management	**2**
PPP.021	**DATABASE LOCK~~FREEZING~~**	The system shall support the freezing (i.e. no data can be entered or edited anymore unless the database is unlocked again) of the entire study database.	Data Management	**2**

PPP.022	**DEVELOPMENT AND PRODUCTION ENVIRONMENT**	The system shall provide a separated development and productive environment.	Data Management	**2**
PPP.023	**DATABASE DEPLOYMENT**	The system shall support the deployment of the database from the development to the productive environment.	Data Management	**2**
PPP.024	**STARTING PAGE**	The study specific starting page shall be configurable, including text and resources.	Data Management	**1**
PPP.025	**DOUBLE DATA ENTRY**	The system shall allow for the (form-specific) configuration of a double data entry workflow.	Data Management	**2**
PPP.026	**eCRF WIZARD**	The system shall support the intuitive creation of eCRFs (i.e. wizard or GUI).	Data Management	**2**
PPP.027	**eCRF LAYOUT WIZARD**	The system shall allow the structuring and organization of items / spaces within the eCRF.	Data Management	**2**
PPP.028	**PRINTING**	All eCRFs within the system shall be printable.	Data Management	**2**
PPP.029	**REPETITIONS / SUB-ENTITIES**	The system shall allow to define elements (i.e. single items, groups of items, whole forms, etc.) that can be repeatedly filled out as many times as necessary.	Data Management	**2**
PPP.030	**BRANCHING LOGIC**	The system shall allow for an intuitive implementation of a branching logic (i.e. the function to show/hide certain fields under a given precondition).	Data Management	**2**
PPP.031	**MULTI-LINGUAL SETUP**	The system shall allow for the assignment of different labels to the same item or default value (i.e. one per language used in the study).	Data Management	**2**
PPP.032	**SURVEYS / PATIENT REPORTED OUTCOMES**	The system offers the possibility to create surveys (i.e. online data entry forms which can be accessed via any browser without login) which can be sent directly to a given patient.	Data Management	**2**
PPP.033	**WEB BASED DATA ENTRY**	The system shall support data entry via online forms.	Data Entry	**2**
PPP.034	**INTERFACE**	The system shall provide a simple and intuitive data entry interface.	Data Entry	**2**
PPP.035	**MISSING DATA**	The system shall offer a mechanism for the handling of missing data.	Data Entry	**2**
PPP.036	**QUERIES**	The system shall allow for queries to be answered by correcting/changing the data and writing a reply. All items that are linked to the queried item through branching logic shall be editable.	Data Entry	**2**

PPP.037	**FORM COMPLETION STATUS**	The system shall support the manual as well as the automatic marking of a form as complete/incomplete/etc..	Data Entry	**2**
PPP.038	**USER WARNINGS**	The system shall issue user warnings before navigation if this were to lead to a loss of data.	Data Entry	**2**
PPP.039	**DATA IMPORT / MIGRATION**	The system shall support import/migration of data into the study database	Data Entry	**2**
PPP.040	**VALIDATION OF IMPORTED DATA**	The system shall offer a feature to run validation on imported data.	Data Entry	**2**
PPP.041	**eCRF COMPLETION STATUS OVERVIEW REPORTS**	The system shall contain overview reports for the tracking of CRF completion status.	Data Entry	**2**
PPP.042	**ERRONEOUS FORMS**	The system shall tag erroneous forms so that they can be recognized without having to open the form.	Monitoring	**2**
PPP.043	**DEVIATION REPORTING**	The system shall allow the reporting of deviations on different levels (e.g. form, visits, item, patient, etc.)	Monitoring	**2**
PPP.044	**QUERY CREATION**	The system shall support the creation of queries (item-, form-, visit-, patient-based).	Monitoring	**2**
PPP.045	**QUERY WORKFLOW**	The system shall allow for queries to be created, closed and withdrawn by the monitor.	Monitoring	**2**
PPP.046	**STUDY PROGRESS REPORT**	The system shall provide a report of study progress key performance indicators (e.g. overall recruitment status, recruitment status per study center, patient status, etc.)	Monitoring	**1**
PPP.047	**QUERY OVERVIEW REPORTS**	The system shall contain overview reports for query management. There should be a direct link from the query list to the form concerned (i.e. by clicking on a query in the query list, you jump directly to the form / data filed for which the query was raised).	Monitoring	**2**
PPP.048	**(S)AE NOTIFICATION**	Expedited notification about reported (S)AEs via e-mail, with link to reported event.	Monitoring	**2**
PPP.049	**SOURCE DATA VERIFICATION**	The system shall support the process of source data verification (SDV) by allowing to report the SDV status for a given data point or an entire form (= massaction). If data points are altered after SDV had already been done (and status set to SDV), the SDV status should change to not SDVd	Monitoring	**2**

PPP.050	**REVIEWING OF FORMS**	The system shall provide the option of reviewing data by two different persons and adding a corresponding tag / status indicator to already reviewed forms	Monitoring	**2**
PPP.051	**RANDOMIZATION MODULE**	The system shall support integrated randomization (standard randomization algorithms, advanced algorithms like minimization)	Statistics	**2**
PPP.052	**UPLOAD OF EXTERNAL RANDOMIZATION LISTS**	The system shall support the upload of an external randomization list (alternative randomization/stratification scheme).	Statistics	**2**
PPP.053	**DATA EXPORT**	The system shall support the exportation of data by CTU or system users (export rights defined in role). The Export file shall contain meta data such as variable and code labels.	Statistics	**2**
PPP.054	**IDENTIFYING DATA**	The system shall provide the option to hide identifying data on a variable level when exporting data	Statistics	**2**
PPP.055	**CONFIGURABLE DATA EXPORT**	The system shall contain a feature to exclusively export monitored/reviewed data.	Statistics	**2**
PPP.056	**DATA EXPORT FORMATS**	The system shall allow the export in various data formats (csv, cdisc stata, R, sas, …)	Statistics	**2**
PPP.057	**API INTERFACE**	The system shall include an API interface.	Statistics	**2**
PPP.058	**REPORT CREATION**	The System shall have the ability to create and modify reports of different types and using both standard data fields, customized data fields (e.g. calculations) and status indicators (e.g. SDV, review status, etc.) or metadata as per study requirements. The number of reports will not be limited.	Statistics	**2**
PPP.059	**GRAPHS CREATION**	The System shall have the ability to create and modify graphs of different types and using both standard and customised data fields as per study requirements. The number of graph tools will not be limited.	Statistics	**1**
PPP.060	**REPORTS**	The system shall include a feature to make reports available to specified user roles only.	Statistics	**2**
PPP.061	**DATA QUALITY REPORTS**	The system shall allow the creation of customized data quality reports (i.e. in order to detect missing data, incomplete forms etc.)	Statistics	**2**

PPP.062	**DATA SAVING**	The system shall offer the possibility to save the entered data at any time.	Data Entry	**2**
PPP.063	**NAVIGATION**	The system shall provide a simple and intuitive way for data entry personnel to navigate the system (e.g. to go from one form to the next, or to go from a form back to the visit plan and vice versa). The user shall always be aware of where he is located and where he can navigate to.	Data Entry	**2**
PPP.064	**CALCULATED FIELDS**	The system shall allow the configuration of calculated fields (e.g. score calculations based on other data entry fields etc.).	Data Management	**2**
PPP.065	**COMMENTS**	The system shall allow additional comments at the level of a form, an item and visit.	Data Entry	**1**
PPP.066	**TIME TILL AUTOMATIC LOG OFF**	The system shall indicate the delay before the system automatically logs the user off.	Data Entry	**2**
PPP.067	**BLINDING OF INDIVIDUAL ROLES**	The system shall allow for blinding of individual user roles.	Data Management	**2**
PPP.068	**EXPORT OF BLINDED PDF**	The system provides the option to extract blinded PDFs (per patient or all patients; complete data or only specific forms, e.g. for adjudication)	Data Management	**2**
PPP.069	**SQL REPORT CREATION**	The system shall support the creation of SQL reports. The system provides a wizard which assists the generation of such reports	Statistics	**2**
REG.001	**VALIDATION**	System Validation documentation and Reports based on Risk Assessment should be approved and available.	Regulatory Requirements	**2**
REG.002	**VALIDATION STANDARDS**	The Validation process for the System should be defined according to pre-defined standards (e.g. Policy, Procedures) and should cover all the relevant steps of the System life cycle.	Regulatory Requirements	**2**
REG.003	**SYSTEM INVENTORY**	The System shall be included in an up-to-date inventory listing of all relevant systems	Regulatory Requirements	**2**
REG.004	**SUPPLIER QUALIFICATION**	Suppliers should be assessed to ensure that the System has been developed in accordance with an appropriate quality management system.	Regulatory Requirements	**2**
REG.005	**USER REQUIREMENTS**	User Requirements Specifications describing the required functions of the System should be present and traceable throughout the lifecycle.	Regulatory Requirements	**2**

REG.006	**VALIDATION TESTING**	Evidence of appropriate test methods and test scenarios should be demonstrated. Particularly, System (process) parameter limits, data limits and error handling should be considered.	Regulatory Requirements	**2**
REG.007	**INCIDENT LOG**	All incidents, not only System failures and data errors, should be reported and assessed. The root cause of a critical incident should be identified and should form the basis of corrective and preventative actions.	Regulatory Requirements	**2**
REG.008	**SYSTEM CHANGE CONTROL**	Any changes to the System, including system configurations should only be made in a controlled manner in accordance with a defined procedure. Validation documentation should include change control records (if applicable) and reports on any deviations observed during the validation process.	Regulatory Requirements	**2**
REG.009	**INVALID RECORD DETECTION**	The System shall allow to discern invalid records.	Regulatory Requirements	**2**
REG.010	**INTERFACE BUILT-IN CHECKS**	In case the System exchanged data electronically with other systems, it shall include appropriate built-in checks for the correct and secure entry and processing of data, in order to minimise the risks.	Regulatory Requirements	**2**
REG.011	**OPERATIONAL CHECKS**	The System shall have operational checks in order to enforce permitted sequencing of steps and events, by allowing the execution of one step only after the execution of the previous one (this requirement applies only if particularly critical operations are performed through the System).	Regulatory Requirements	**2**
REG.012	**ACCURACY CHECKS**	In case of critical data manually entered, an additional check done by a second operator or by validated electronic means on the accuracy of data shall be done. The criticality and the potential consequences of erroneous or incorrectly entered data to a system shall be covered by risk management.	Regulatory Requirements	**2**

REG.013	**BACKUP**	Backup and recovery procedure shall be defined where temporal periods for data backup are defined. Regular backups of all relevant data shall be done. Integrity and accuracy of backup data shall be monitored periodically.	Regulatory Requirements	**2**
REG.014	**DATA RESTORE**	The ability to restore the data shall be checked during validation and monitored periodically.	Regulatory Requirements	**2**
REG.015	**DATA RETENTION**	Data shall be secured by both physical and electronic means against damage. The System shall allow to store electronic records to enable their accurate and ready retrieval throughout the records retention period.	Regulatory Requirements	**2**
REG.016	**BUSINESS CONTINUITY**	Provisions shall be made to ensure continuity of support for critical processes in the event of a system breakdown (e.g. a manual or alternative system). The time required to bring the alternative arrangements into use should be based on risk and appropriate for a particular system and the business process it supports. These arrangements shall be adequately documented and tested.	Regulatory Requirements	**2**
REG.017	**RESTRICTED ACCESS**	The System shall restrict access to pre-authorised users. The extent of security controls depends on the criticality of the System.	Regulatory Requirements	**2**
REG.018	**RESTRICTED USE**	The System shall restrict use of its functions according to pre-configured user profiles that are maintained. Any changes to the roles shall be authorised and tracked.	Regulatory Requirements	**2**
REG.019	**USER PROFILES SECURITY**	Creation, change and cancellation of access authorisations and user profiles (i.e. functions users are able to use) shall be traced according to a pre-defined procedure.	Regulatory Requirements	**2**
REG.020	**PASSWORD ASSIGNMENT**	Password shall be known only by the user. When a new password is assigned by the System administrator, the System shall force user to change his password after the first login.	Regulatory Requirements	**2**
REG.021	**AUTOMATIC LOG OFF**	The System shall include a log off mechanism after a pre-defined period of user inactivity, or a mechanism where user ID entry is required after inactivity period.	Regulatory Requirements	**2**

REG.022	**USERNAME & CODE CONTROL**	The System shall ensure that identification code and password are periodically checked, recalled, or revised.	Regulatory Requirements	**2**
REG.023	**ACCESS DENIED**	The System shall electronically de-authorise access when an incorrect combination of identification code and password is repeated a defined number of times. Re-assignment of password should be managed by an adequate procedure.	Regulatory Requirements	**2**
REG.024	**UNAUTHORISED ACCESS DETECTION**	The System shall detect and report in an immediate and urgent manner any attempts at unauthorised use of identification codes and password to the System security unit, and, as appropriate, to organisational management.	Regulatory Requirements	**2**
REG.025	**UNIQUENESS OF CODES**	The System shall maintain the uniqueness of each combined identification code and password, such that no two individuals have the same combination of identification code and password.	Regulatory Requirements	**2**
REG.026	**TEMPORAL REFERENCE**	The System shall ensure that the time reference is equal for all users, or it shall automatically synchronise all work stations. The System shall not allow the users to change the time reference.	Regulatory Requirements	**2**
REG.027	**RECORD AUDIT TRAIL**	System Audit Trail, based on a risk assessment, tracing all relevant GCP changes and deletion shall be in place through automatic functionality. Audit Trail shall record operators creating, changing, confirming or deleting data including date and time ensuring that previous record changes are not overwritten. Audit trail documentation shall be retained throughout the records retention period.	Regulatory Requirements	**2**
REG.028	**AUDIT TRAIL COPY**	The System shall allow to create accurate and complete copies of audit trail in a standard file format (e.g. PDF…).	Regulatory Requirements	**2**
REG.029	**AUDIT TRAIL REVIEW**	Audit trails need to be available and convertible to a generally intelligible form and regularly reviewed.	Regulatory Requirements	**2**

SPR.001	**QUALITY MANAGEMENT SYSTEMS CERTIFICATION**	The Supplier (including affiliates and subcontractors) shall work at all times according to ISO 9001 certification, GCP (Good Clinical Practice), GDPR or any other standard relevant to the applicable scope of the agreement.	Supplier Profile Requirements	**2**
SPR.002	**COMPLIANCE TO GAMP® 5**	The Supplier shall have a QMS (Quality Management System) and a product development lifecycle complying with computerized systems and engineering best practices described in GAMP® 5.	Supplier Profile Requirements	**2**
SPR.003	**INITIAL COSTS**	The supplier shall give an approximation of initial setup costs for one installation.	Supplier Profile Requirements	**2**
SPR.004	**ANNUAL COSTS**	The supplier shall describe how annual costs are calculated for a single customer	Supplier Profile Requirements	**2**
SPR.005	**LICENCE MODEL**	The supplier shall describe the applied licence model.	Supplier Profile Requirements	**2**
SPR.006	**DATABASE MANAGEMENT SYSTEM USED**	The supplier shall describe what kind of database management system he uses (e.g., SQL, Oracle, etc.)	Supplier Profile Requirements	**2**