CENTRAXX® TRIAL/CTMS

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THE BETTER THE SOFTWARE, THE MORE SUCCESSFUL THE STUDY – CENTRAXX® TRIAL.

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The first challenges to study design can emerge as early as the project planning phase. Recruiting enough suitable patients or test persons, for example, can be complicated and confusing. CentraXX Trial offers a solution which improves patient analysis and makes recruitment more effective. CentraXX Trial can map all relevant points of study design (including eCRF modeling) from population-based, health care-related, and clinical studies.

Rule-based and individualized study processes can be created using the built in rights-based access control, eCRF Designer and randomization functions. While collecting study data, the user works via intelligent forms, which they may view and edit according to their specified user role. Validation rules from simple to very complex and automatically detected discrepancies are integral parts of CentraXX Trial. This leads to significant improvements in the entire workflow and data quality. Data entry is verified automatically and CRFs can be finalized, released, reviewed, or locked depending on the role of the user.

Task lists and statuses allow the processing status of each patient to be checked at any time. In addition, the CentraXX study module can always be linked to all other CentraXX system modules so that, among other things, the creation and receipt of sample collection kits is documented and so that the medical data already known to the study participants can be used directly.

A prerequisite for campus-wide or cross-site recruitment is the registration and clear presentation of all available content in a web portal. In the central Study Register, various study profiles from a variety of departments can be flexibly displayed and managed according to the designated rights of the user. The inclusion and exclusion criteria of all studies are structured, as much as possible, so that these criteria can be compared with the entire patient/test person population in CentraXX in order to promptly find potential study participants.

Would you like to find out more about the CentraXX TRIAL/CTMS? Or are you already a CentraXX user and would like to integrate this module into your existing CentraXX architecture?

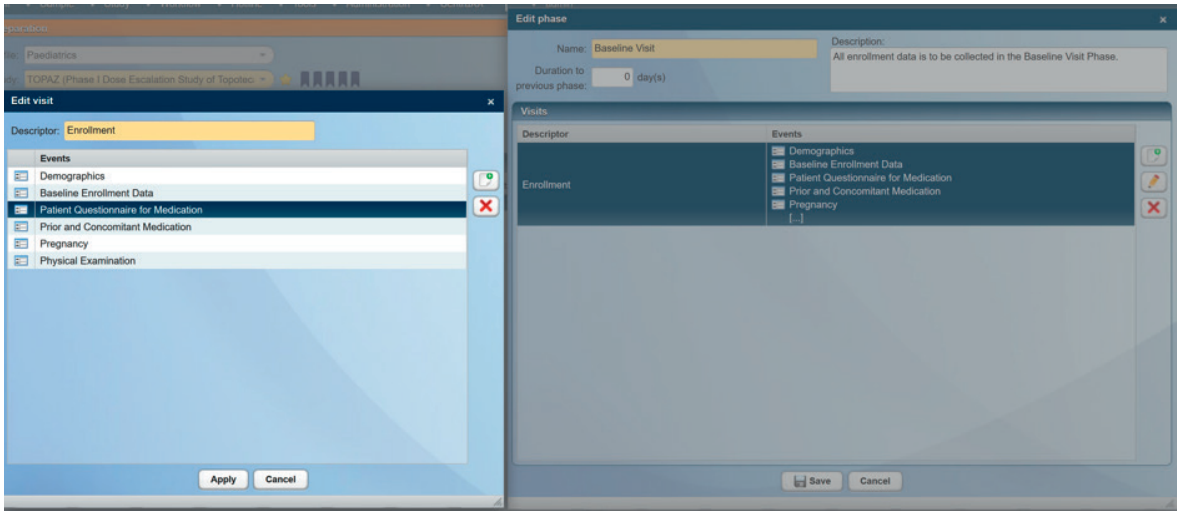
Then please contact KAIROS >info@kairos.us

NOW IS THE TIME. **> kairos.us**

CENTRAXX® TRIAL OVERVIEW

PHASE 1 Project/Study Definition

CentraXX has a lot to offer from the moment of defining the study and study criteria. Combining this information with available data through queries, searches and analyses helps evaluate the feasibility of a study. CentraXX users can determine the number of participants in comparable past studies and assess how recruitment would have turned out in the past. This allows users to eliminate "low performing clinical trials" during the study definition stage.



Tool-based study preparation in CentraXX

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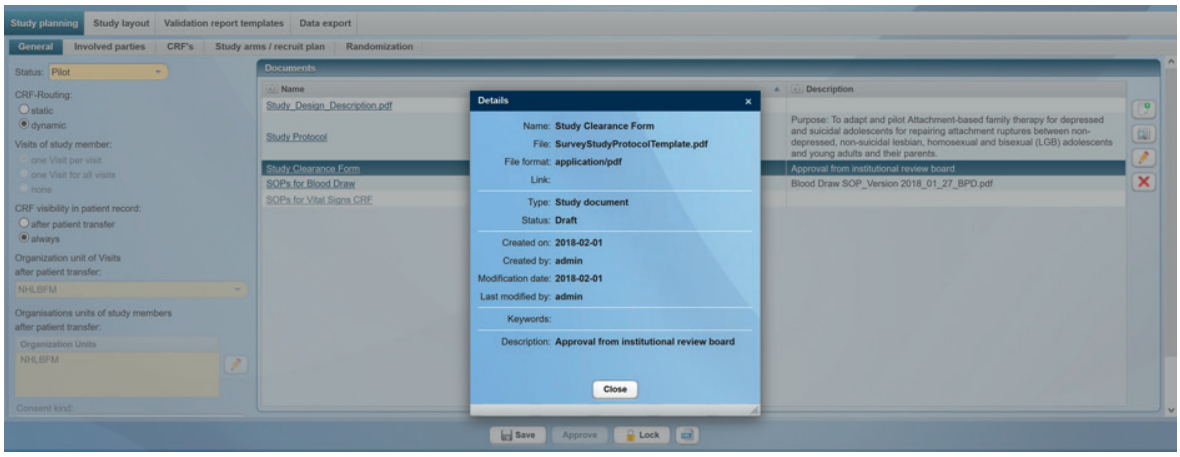
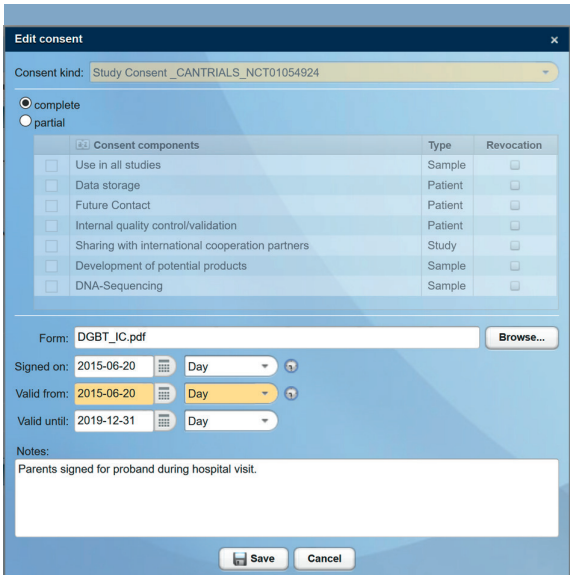
PHASE 2 Releases

As soon as studies are approved by the ethics committee or by a sponsor, the corresponding documents can be added to the study and selected project members will be able to access them anytime and anywhere. Users can then design the consent forms structured in the system.



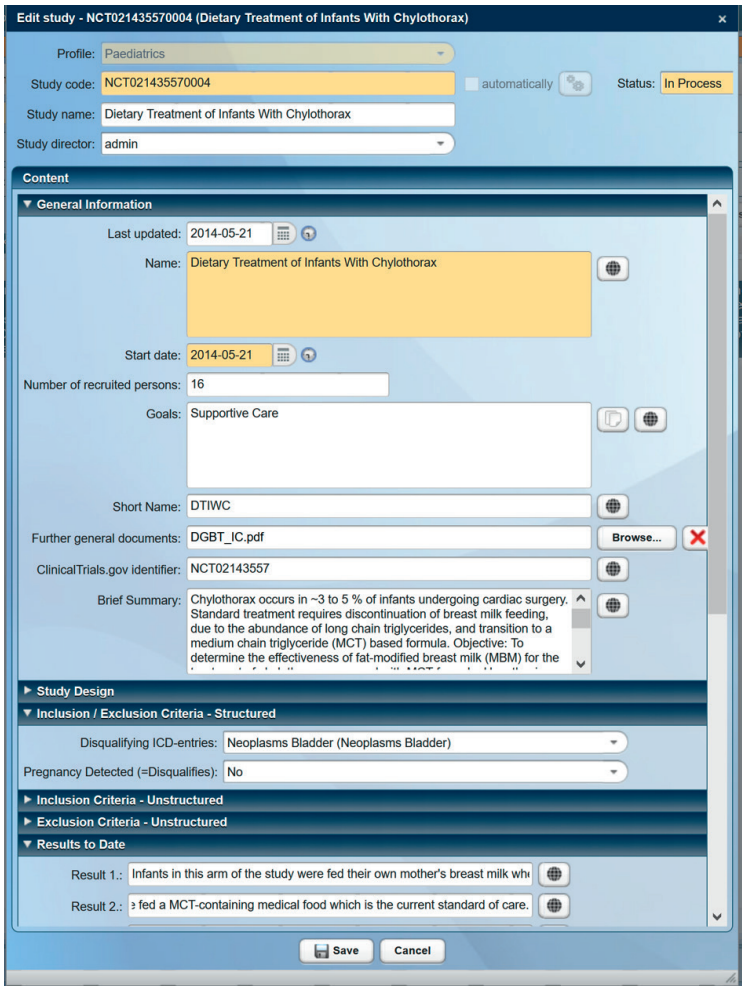
Storage and presentation of study release documents (Ethics Committee/Sponsor)



Structured recording and presentation of declarations of consent

PHASE 3 Project / Study Initiation

Using a web-based administration tool, CentraXX users with minimal IT knowledge can manage the study participants and resources for a study without long delays. The CentraXX Study Register allows all authorized persons immediate access to important study information such as inclusion and exclusion criteria.



Structured recording and presentation of studies in the study register

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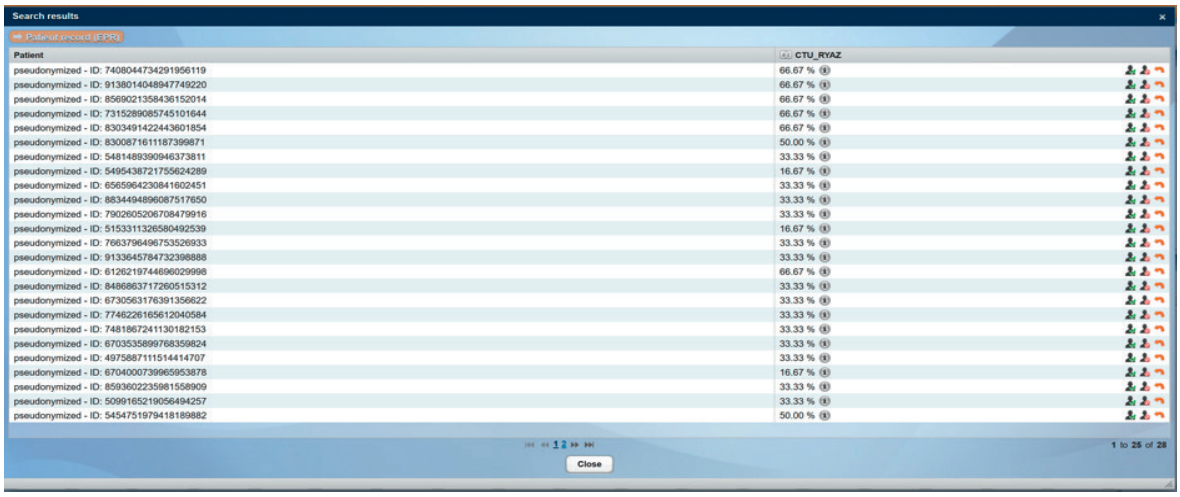
PHASE 4 Patient Recruiting

CentraXX Trial contains an advanced recruiting tool. Anonymous admission data is queried and patients are displayed anonymously by the system as study participants at any time if they correspond to the inclusion and exclusion criteria. Users can draw the attention of the attending physician to a study and ask for support with recruitment.



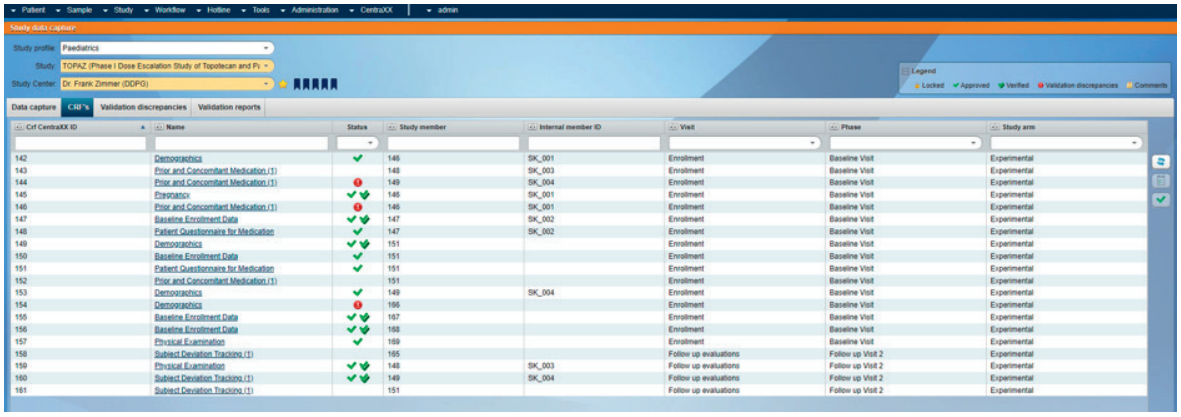
Anonymous representation of suitable study participants

PHASE 5 Project/Study Implementation

The eCRF Designer is the central element of the CTMS. It allows for flexible design of the forms required for study documentation. CentraXX Trial supports the entire life cycle of electronic Case Report Forms (eCRFs) from signing, testing and use to archiving and subsequent versioning. This functionality and life cycle approach is tightly integrated with the many other tools and functionalities and reflects the CentraXX implementation concept. The eCRF-Designer is linked to the Workflow/Rules Engine and Data Dictionary, as well as additional essential functions such as:

- **Discrepancy Management and Reporting**
- **CRF-Monitoring**
- **Job- Controlled Review**
- **Documentation of Adverse Events**

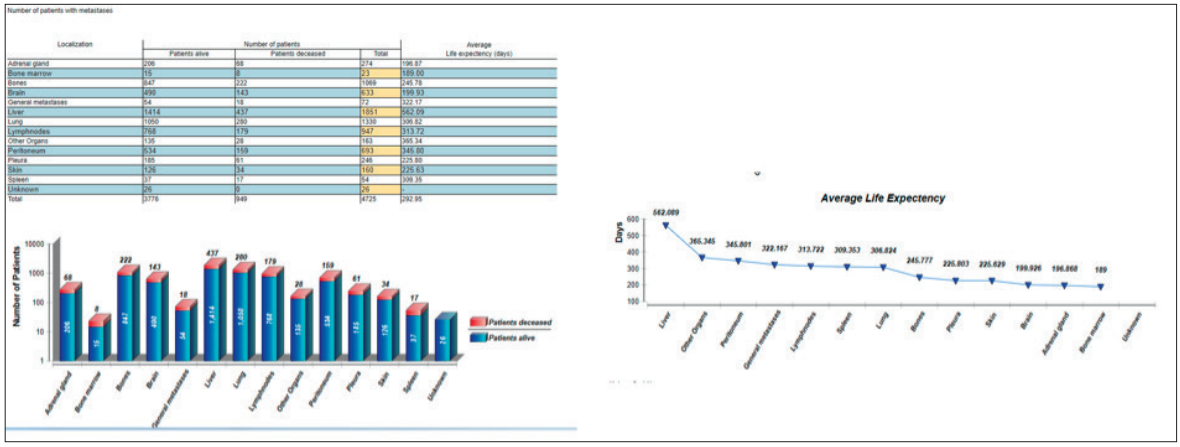
In addition to the documentation and monitoring of the study, it is always important to receive management information. If users want to query and analyze important key figures for all studies in an institution, the CentraXX reporting tool can help.



Presentation of validation violations in already documented eCRFs

PHASE 6 Study Results

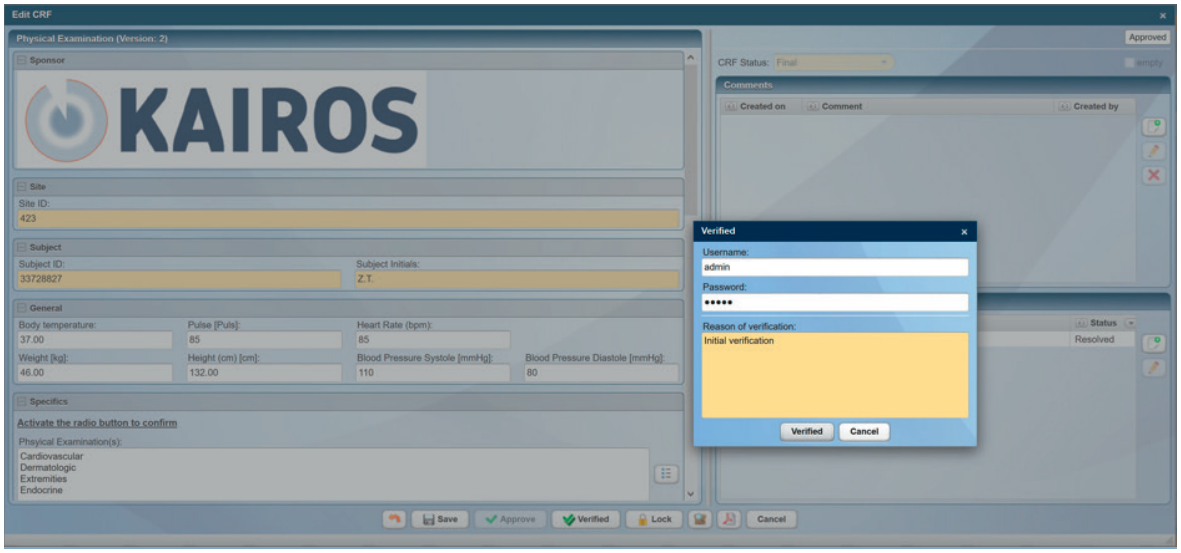
Study results are not presented in silos. Rather, they are viewed alongside results from previous and ongoing studies. This allows for a comparison of studies with similar results. This way, users can carry out the important benchmarking for further studies in the CentraXX system.



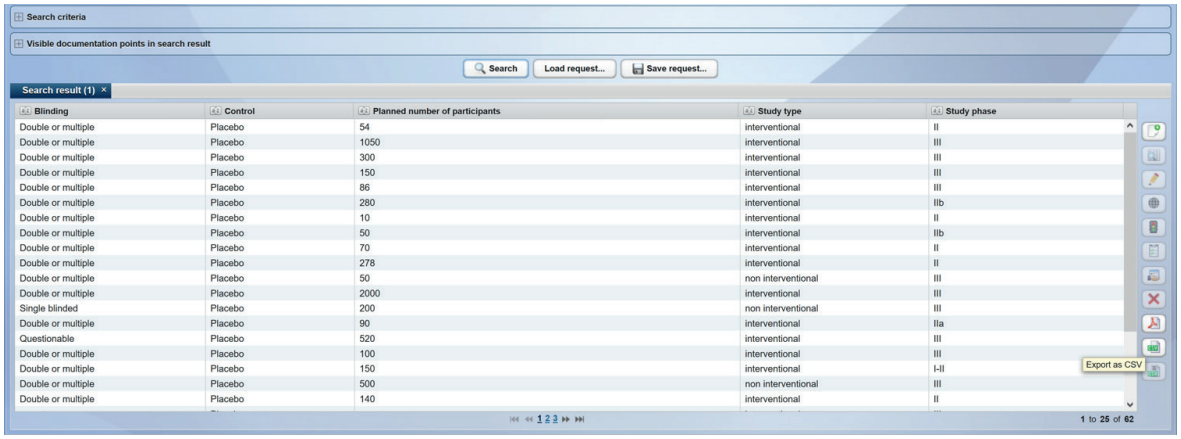
Presentation of study results in graphs and tables

PHASE 7 Release of Results

In the end, the user wants a very simple publication of their results. The CentraXX publication assistance works similarly to the description of the findings written in daily clinical practice. This functionality allows users to select all important results and export them for use in other software solutions.



Verification of the results by the user



Presentation of the selected study results for export for further use in other software solutions

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