

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



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.

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.

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.

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.

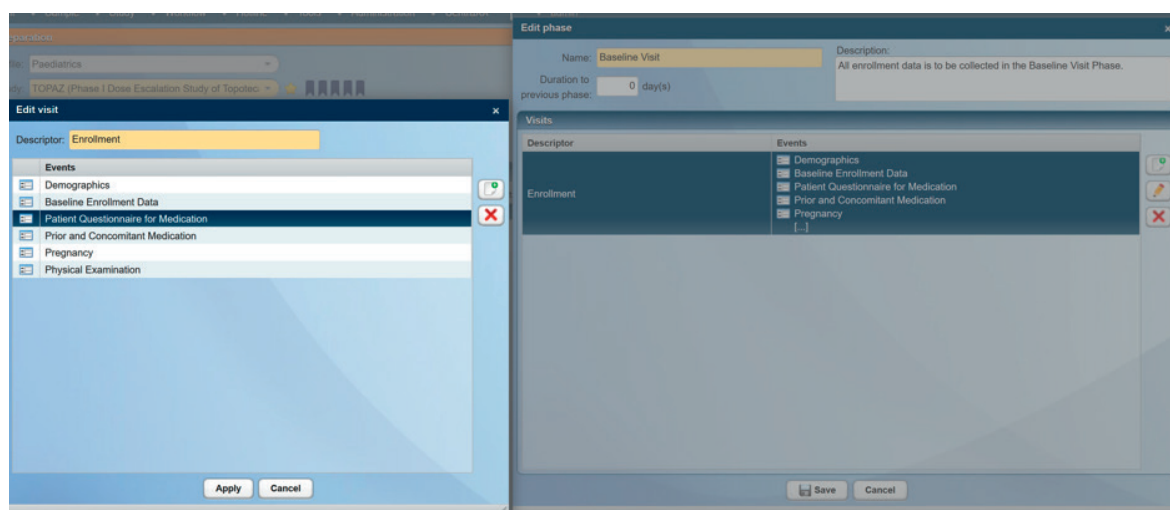
> kairos.us

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.

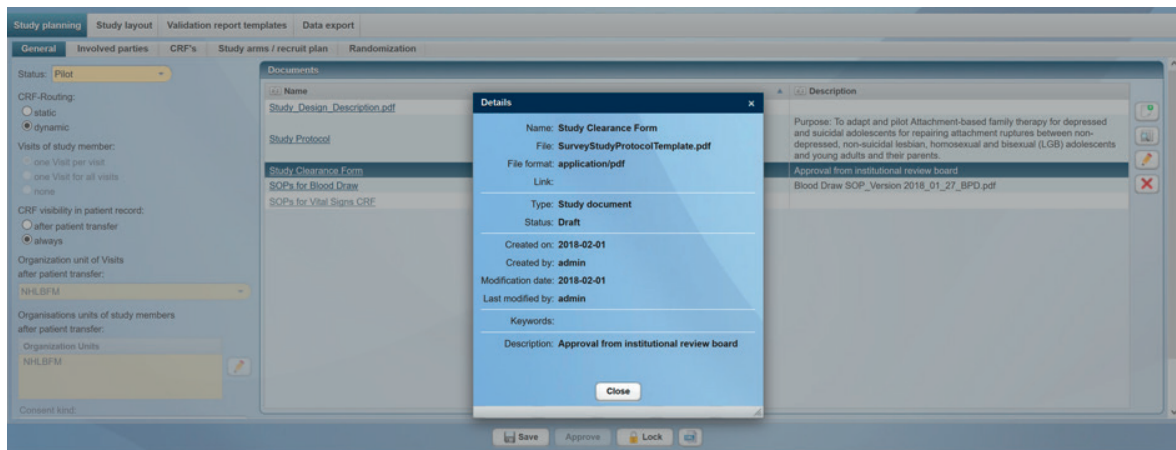


Tool-based study preparation in CentraXX

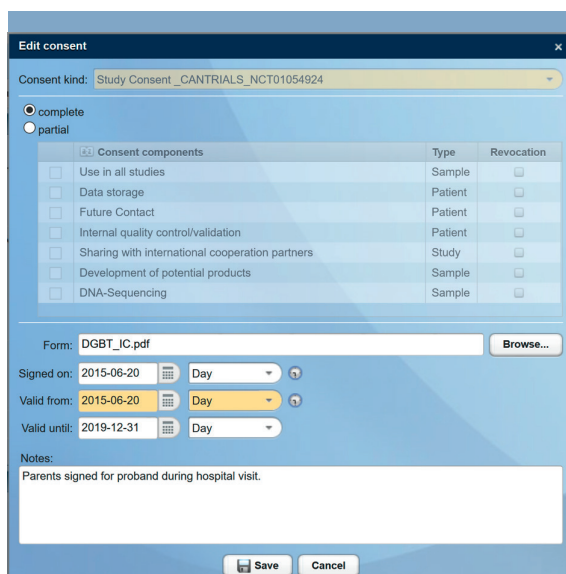
PHASE 2 Releases

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)



Consent components	Type	Revocation
<input type="checkbox"/> Use in all studies	Sample	<input type="checkbox"/>
<input type="checkbox"/> Data storage	Patient	<input type="checkbox"/>
<input type="checkbox"/> Future Contact	Patient	<input type="checkbox"/>
<input type="checkbox"/> Internal quality control/validation	Patient	<input type="checkbox"/>
<input type="checkbox"/> Sharing with international cooperation partners	Study	<input type="checkbox"/>
<input type="checkbox"/> Development of potential products	Sample	<input type="checkbox"/>
<input type="checkbox"/> DNA-Sequencing	Sample	<input type="checkbox"/>

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.

Edit study - NCT021435570004 (Dietary Treatment of Infants With Chylothorax)

Profile: Paediatrics
 Study code: NCT021435570004 ☐ automatically Status: In Process
 Study name: Dietary Treatment of Infants With Chylothorax
 Study director: admin

Content

General Information

Last updated: 2014-05-21
 Name: Dietary Treatment of Infants With Chylothorax
 Start date: 2014-05-21
 Number of recruited persons: 16
 Goals: Supportive Care
 Short Name: DTIWC
 Further general documents: DGBT_IC.pdf Browse...
 ClinicalTrials.gov identifier: NCT02143557
 Brief Summary: Chylothorax occurs in ~3 to 5 % of infants undergoing cardiac surgery. Standard treatment requires discontinuation of breast milk feeding, due to the abundance of long chain triglycerides, and transition to a medium chain triglyceride (MCT) based formula. Objective: To determine the effectiveness of fat-modified breast milk (MBM) for the

Study Design

Inclusion / Exclusion Criteria - Structured

Disqualifying ICD-entries: Neoplasms Bladder (Neoplasms Bladder)
 Pregnancy Detected (=Disqualifies): No

Inclusion Criteria - Unstructured

Exclusion Criteria - Unstructured

Results to Date

Result 1.: Infants in this arm of the study were fed their own mother's breast milk whi
 Result 2.: fed a MCT-containing medical food which is the current standard of care.

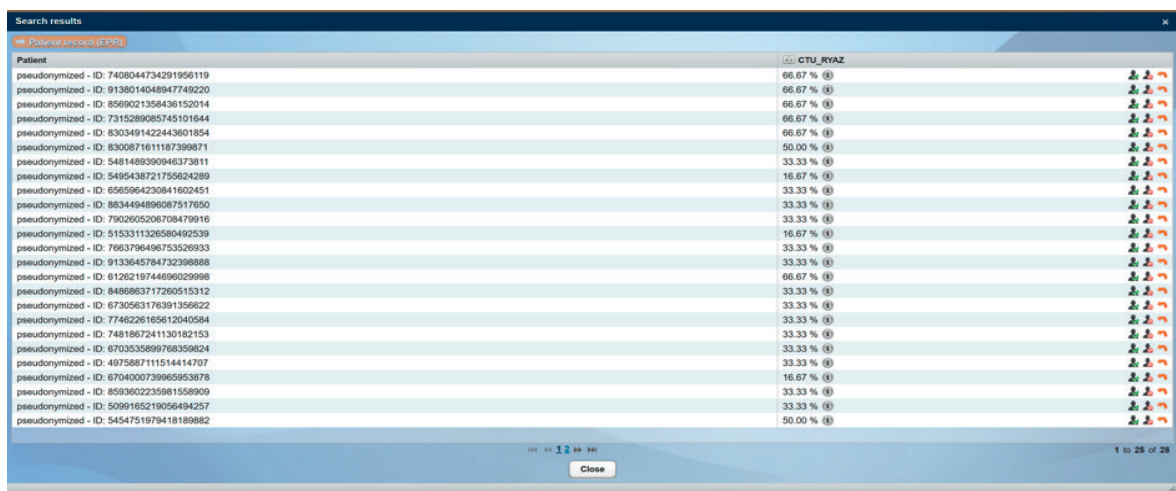
Save Cancel

Structured recording and presentation of studies in the study register

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.



Patient	CTU_RVAZ	Status
pseudonymized - ID: 7408044734201956119	66.67 %	👤👤👤
pseudonymized - ID: 9138014048947749220	66.67 %	👤👤👤
pseudonymized - ID: 8569021358436152014	66.67 %	👤👤👤
pseudonymized - ID: 7315289085745101644	66.67 %	👤👤👤
pseudonymized - ID: 8303491422443601854	66.67 %	👤👤👤
pseudonymized - ID: 8300871611187399871	50.00 %	👤👤👤
pseudonymized - ID: 5481480390046373811	33.33 %	👤👤👤
pseudonymized - ID: 5495438721755624289	16.67 %	👤👤👤
pseudonymized - ID: 6565964230841602451	33.33 %	👤👤👤
pseudonymized - ID: 883449489967517650	33.33 %	👤👤👤
pseudonymized - ID: 7902805206708479916	33.33 %	👤👤👤
pseudonymized - ID: 5153311326580492539	16.67 %	👤👤👤
pseudonymized - ID: 7663796496753526933	33.33 %	👤👤👤
pseudonymized - ID: 9133645784732398888	33.33 %	👤👤👤
pseudonymized - ID: 6126219744690029998	66.67 %	👤👤👤
pseudonymized - ID: 8486863717260515312	33.33 %	👤👤👤
pseudonymized - ID: 6730563176391356622	33.33 %	👤👤👤
pseudonymized - ID: 7746226165612040584	33.33 %	👤👤👤
pseudonymized - ID: 7481867241130182153	33.33 %	👤👤👤
pseudonymized - ID: 6703535899768359824	33.33 %	👤👤👤
pseudonymized - ID: 4975887111514414707	33.33 %	👤👤👤
pseudonymized - ID: 6704000739965953878	16.67 %	👤👤👤
pseudonymized - ID: 8593602235981558909	33.33 %	👤👤👤
pseudonymized - ID: 5099165219056494257	33.33 %	👤👤👤
pseudonymized - ID: 5454751979418189882	50.00 %	👤👤👤

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.

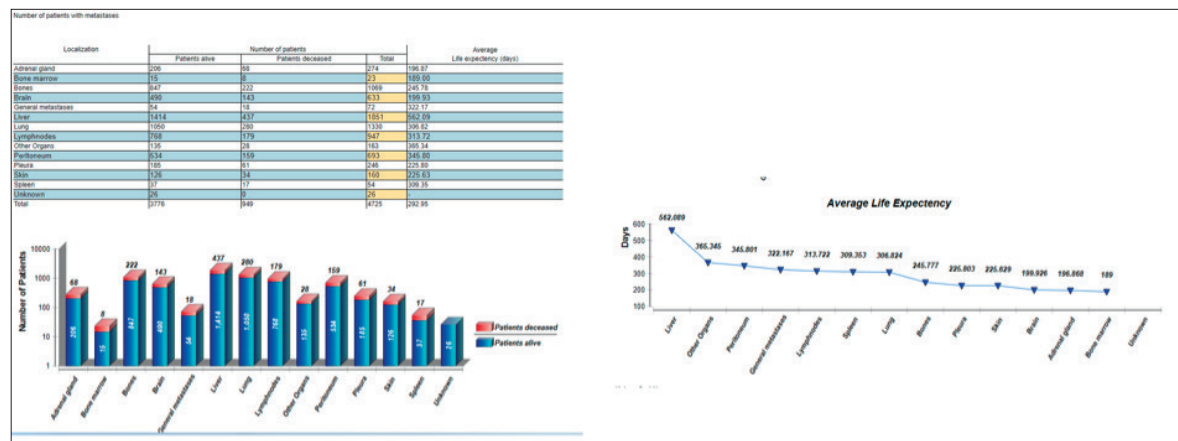
CRF CentraXX ID	Name	Status	Study member	Internal member ID	Visit	Phase	Study arm
142	Demographics	✓	148	SK_001	Enrollment	Baseline Visit	Experimental
143	Prior and Concomitant Medication (1)	✓	148	SK_003	Enrollment	Baseline Visit	Experimental
144	Prior and Concomitant Medication (1)	✗	149	SK_004	Enrollment	Baseline Visit	Experimental
145	Physician	✓	148	SK_001	Enrollment	Baseline Visit	Experimental
146	Prior and Concomitant Medication (1)	✓	148	SK_001	Enrollment	Baseline Visit	Experimental
147	Baseline Enrollment Data	✓	147	SK_002	Enrollment	Baseline Visit	Experimental
148	Patient Questionnaire for Medication	✓	147	SK_002	Enrollment	Baseline Visit	Experimental
149	Demographics	✓	151		Enrollment	Baseline Visit	Experimental
150	Baseline Enrollment Data	✓	151		Enrollment	Baseline Visit	Experimental
151	Patient Questionnaire for Medication	✓	151		Enrollment	Baseline Visit	Experimental
152	Prior and Concomitant Medication (1)	✓	151		Enrollment	Baseline Visit	Experimental
153	Demographics	✓	149	SK_004	Enrollment	Baseline Visit	Experimental
154	Demographics	✗	150		Enrollment	Baseline Visit	Experimental
155	Baseline Enrollment Data	✓	157		Enrollment	Baseline Visit	Experimental
156	Baseline Enrollment Data	✓	158		Enrollment	Baseline Visit	Experimental
157	Physical Examination	✓	159		Enrollment	Baseline Visit	Experimental
158	Subject Deviation Tracking (1)	✓	155		Follow up evaluations	Follow up Visit 2	Experimental
159	Physical Examination	✓	149	SK_003	Follow up evaluations	Follow up Visit 2	Experimental
160	Subject Deviation Tracking (1)	✓	149	SK_004	Follow up evaluations	Follow up Visit 2	Experimental
161	Subject Deviation Tracking (1)	✓	151		Follow up evaluations	Follow up Visit 2	Experimental

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.

The screenshot shows the 'Edit CRF' interface for a 'Physical Examination (Version: 2)' form. The form includes fields for Sponsor (KAIRO), Site ID (423), Subject ID (3372827), and Subject Initials (Z.T.). It also contains a 'General' section with fields for Body temperature, Pulse, Heart Rate, Weight, Height, Blood Pressure Systole, and Blood Pressure Diastole. A 'Specifics' section is partially visible. A 'Verified' dialog box is open, prompting for Username (admin), Password (*****), and Reason of verification (Initial verification). The dialog has 'Verified' and 'Cancel' buttons. The background form has a 'CRF Status' dropdown set to 'Final' and a 'Comments' section. At the bottom, there are buttons for Save, Approve, Verified, Lock, and Cancel.

Verification of the results by the user

The screenshot shows the search results interface. At the top, there are search criteria and a 'Visible documentation points in search result' section. Below this is a table with the following columns: Blinding, Control, Planned number of participants, Study type, and Study phase. The table contains 15 rows of data. An 'Export as CSV' button is visible in the bottom right corner.

Blinding	Control	Planned number of participants	Study type	Study phase
Double or multiple	Placebo	54	interventional	II
Double or multiple	Placebo	1050	interventional	III
Double or multiple	Placebo	300	interventional	III
Double or multiple	Placebo	150	interventional	III
Double or multiple	Placebo	96	interventional	III
Double or multiple	Placebo	280	interventional	IIb
Double or multiple	Placebo	10	interventional	IIb
Double or multiple	Placebo	50	interventional	IIb
Double or multiple	Placebo	70	interventional	II
Double or multiple	Placebo	278	interventional	II
Double or multiple	Placebo	50	non interventional	III
Double or multiple	Placebo	2000	interventional	III
Single blinded	Placebo	200	non interventional	III
Double or multiple	Placebo	90	interventional	IIa
Questionable	Placebo	520	interventional	III
Double or multiple	Placebo	100	interventional	III
Double or multiple	Placebo	150	interventional	I-II
Double or multiple	Placebo	500	non interventional	III
Double or multiple	Placebo	140	interventional	II

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

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