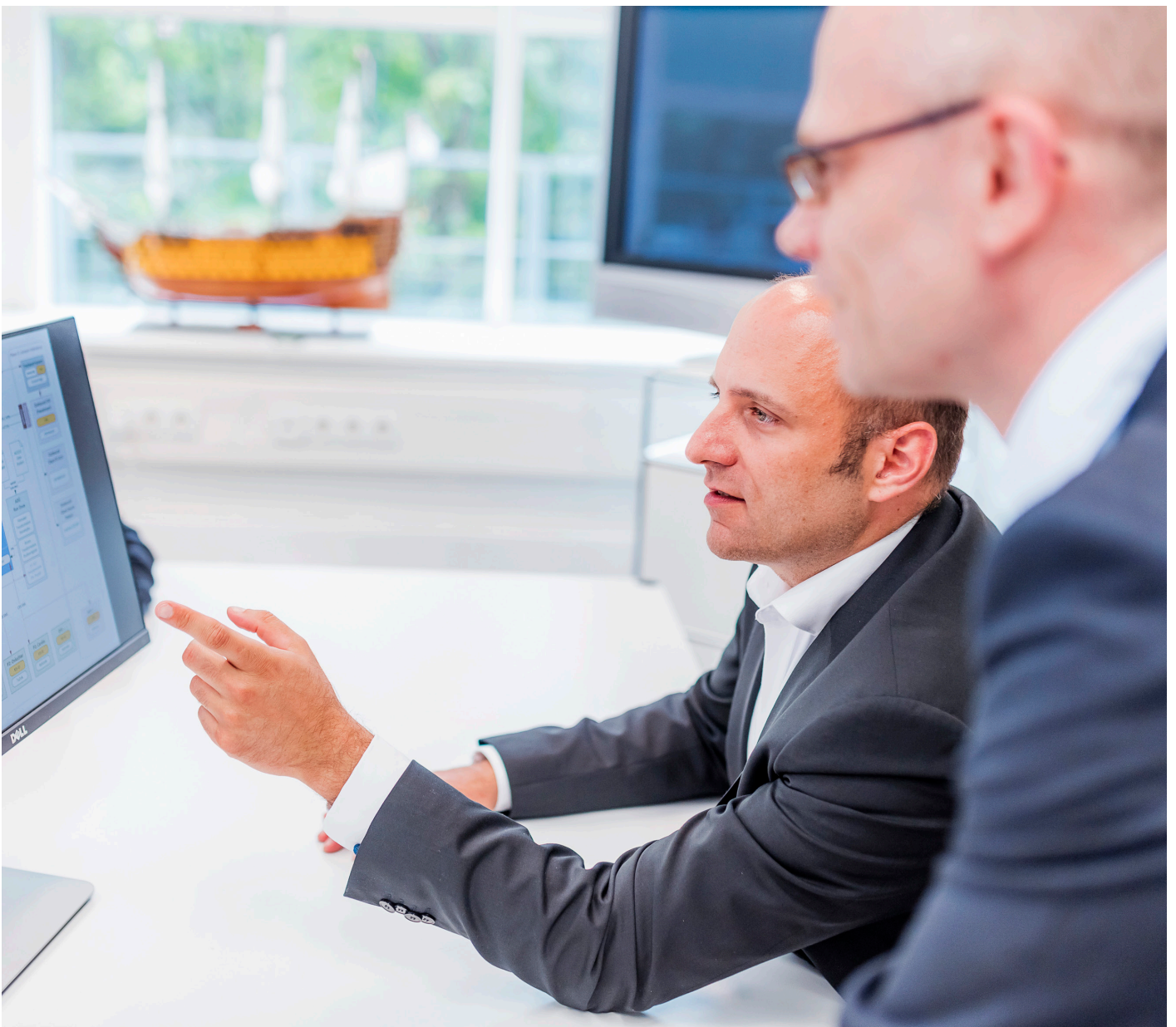


CENTRAXX® FROM SPECIALISTS FOR EXPERTS.



CentraXX Basic - Researchers working today to more effectively combat major widespread diseases need both a redefined infrastructural environment and newly designed technical equipment. Only if properly equipped will their research results spearhead scientific progress. A great development in this direction came with the establishment of the six German Health Research Centers (DZG), which have focused on establishing cross-departmental Translational Medicine. The

aim of these centers is to help patients benefit more quickly from medical therapies and products. The active, barrier-free, and constant exchange of information between medical treatment and research is the first prerequisite for laboratory research results to more quickly benefit the medical field in the future. There is great demand for this kind of translation as reflected in the motto „From Bench to Bedside“. It is vital that new system IT solutions are developed and implemented to meet these requirements.

THE PROBLEM

While there have been many IT solutions and providers on the clinical side (e.g. for the HIS/CWS systems required in hospitals), relatively few suitable IT solutions have been developed on the research end.

THE APPROACH

Expertise across disciplines from science, clinics and industry must be brought together to develop new methods and tools to address the real challenges of curative treatment. This approach paves the way for improved prevention and diagnosis to lead to individualized treatment and finally to personalized medicine.

THE HURDLES

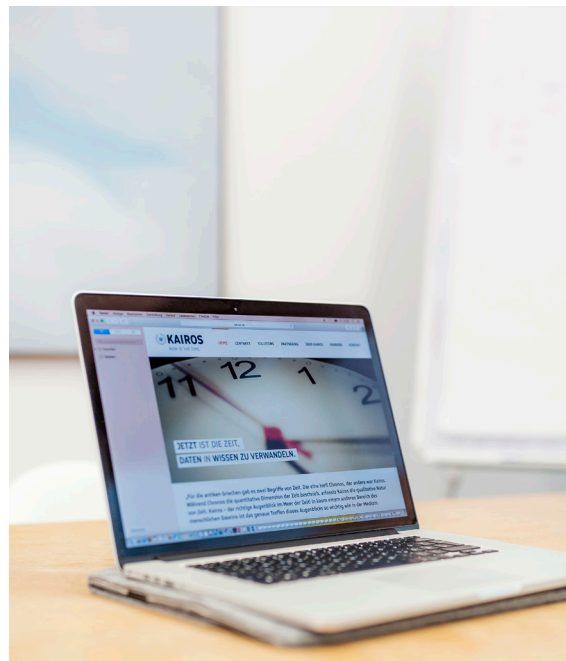
Many medical institutions still use technically outdated and even stand-alone IT solutions, which were originally developed for other purposes, such as the documentation and administration of patient data for billing purposes in the clinic. These IT systems cannot be integrated into the kind of information network that is so greatly needed to improve medical treatment. However, the issue of system interoperability is not the only obstacle. In addition to the lack of uniform programming standards and the wide variety of interface requirements, the need for cross-platform, standardized vocabulary (keyword: Data Dictionary) and a common interpretation of the data (keyword: Meta Data Definition) are still major practical challenges when networking different locations or system solutions. Another challenge arises from the fact that existing primary and secondary systems are not built to cope with the ever-increasing amount of (unstructured) data.

CENTRAXX® – THE KAIROS SOLUTION

With the software product CentraXX, KAIROS offers a biomedical research portal with the principles of personalized medicine already anchored in its product DNA.

The CentraXX research portal focuses on the structured recording of research content using the biobanking and study management modules. A comprehensive data capturing pipeline is used to establish a connection to treatment-related data. It is precisely the provision of treatment-related data for research that helps data be viewed within a larger context. The portal thus offers the ability to conduct important evaluations, such as comparisons of patients with similar or partially related cases. This is important as already today, characteristics such as age, diagnosis, therapy, pathological descriptions and laboratory values are no longer enough to compare diseases within the framework of personalized medicine.

Therefore, a research portal should be able to integrate OMICS procedures. Such a symbiosis could provide IT-supported predictions and therapy proposals. This is another reason why KAIROS has implemented a certified QMS according to DIN ISO 13485 for the development of medical products, allowing research data to be fed back into the treatment process. This data integration cycle is the basis for successful personalized medicine.



Would you like to find out more about the CentraXX BASIC? 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.

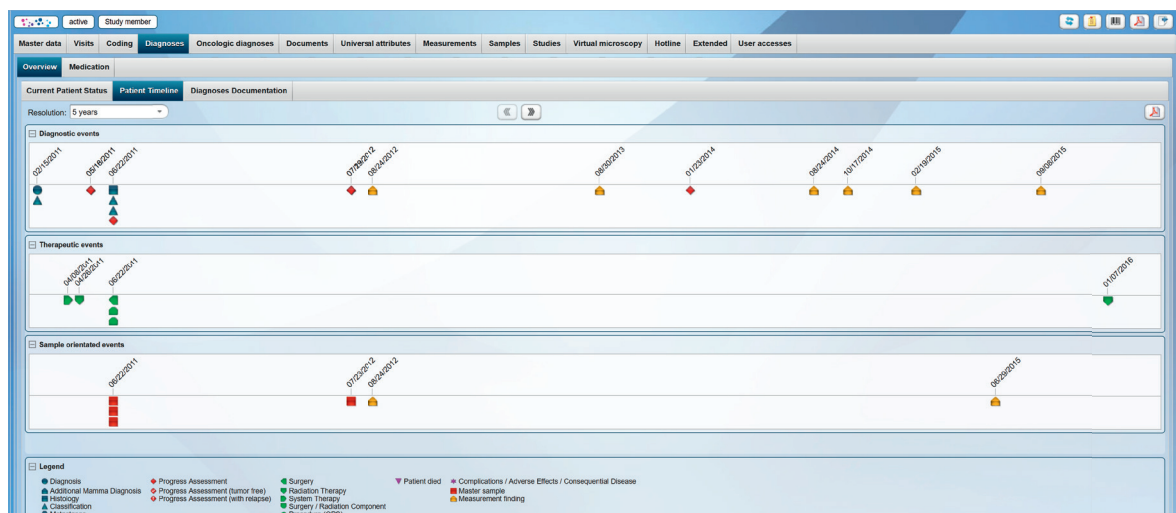
> kairos.us

THE CENTRAXX® – KEY FUNCTIONAL ELEMENTS:

Research Records

The EPR (Electronic Patient Record) is the central storage unit in CentraXX. All sample information collected in CentraXX Bio and all study data collected on registered CentraXX patients/subjects in CentraXX Trial are embedded in the EPR. This is how CentraXX makes the longitudinal data of a patient accessible rather than leave data to be viewed as isolated snapshots. In addition to sample and study information of an

individual patient/subject, other structured data from diagnoses (e.g. ICD10), procedures (e.g. OPS), episodes (e.g. inpatient stays), medication, declarations of consent, virtual microscopy, and the hotline are combined in the same file. It is possible to upload all kinds of documents (e.g. signed consent forms) into the Research Record.



The data timeline of a patient

Forms Engine

In addition to the CentraXX standard masks for capturing patient and sample-related data, the embedded forms engine offers the option of flexibly creating masks for capturing all additional documentation points required. Measurement profiles,

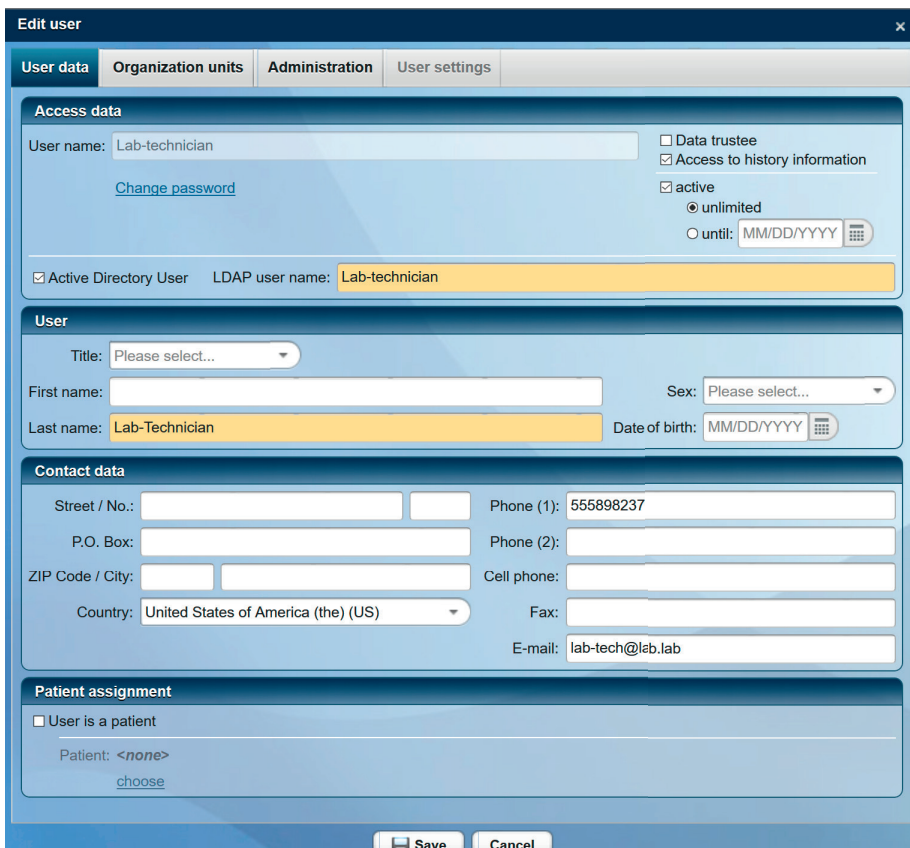
consisting of measurement parameters of different types, can be designed in this user interface. The data captured with these forms can be found ad-hoc with the query engine in CentraXX.

A self-designed form for capturing additional data points

User Administration

CentraXX offers the possibility to create and manage different user groups. Users with different rights, such as “attending physician” or “research student,” can be created and managed in the system. Each user can be assigned an e-mail to enable password recovery and to receive reports or notifications of new tasks in the system. Users can also be registered as data trustees, enabling them to match pseudonymized

IDs with identifying ones and to access audit tables in specific areas (e.g., sample documentation and measurement findings). A user can also be linked to a patient in the system. This means that a patient could register directly with CentraXX to fill in self-assessment forms in the system or to view their data collected in CentraXX. A time limit can be set for temporary users created in the system.



Edit user

User data | **Organization units** | **Administration** | **User settings**

Access data

User name: Lab-technician ☐ Data trustee
☒ Access to history information
[Change password](#)
☒ active
☒ unlimited
☐ until: MM/DD/YYYY

☒ Active Directory User LDAP user name: Lab-technician

User

Title: Please select...
 First name: Sex: Please select...
 Last name: Lab-Technician Date of birth: MM/DD/YYYY

Contact data

Street / No.: Phone (1): 555898237
 P.O. Box: Phone (2):
 ZIP Code / City: Cell phone:
 Country: United States of America (the) (US) Fax:
 E-mail: lab-tech@lab.lab

Patient assignment

☐ User is a patient
 Patient: <none>
[choose](#)

Save **Cancel**

User administration in CentraXX

Client Management

CentraXX supports the separation of multiple clients by grouping patients and samples into organizational units. All users are assigned organizational units, which ensures that only users with specific access rights to their departments may view the

corresponding and relevant data of their patient groups. This is how CentraXX enables larger institutions to collect data on the same patient across departments without fear of sensitive data being accessed by unauthorized users.

Pseudonymization Service

CentraXX offers an integrated pseudonymization service. All identifying patient data is stored in a separate database. Users can have access to patient files without seeing identifying data. CentraXX offers various strategies to comply with the strictest data

protection guidelines. For example, it is possible to integrate external trusteeships and have separate CentraXX instances synchronized with each other to ensure that no identifying data can ever be viewed by unauthorized personnel.

The screenshot displays the CentraXX Demo application interface. On the left, there is a sidebar with search criteria including Patient ID, MRN, CentraXX Patient ID, First name, Last name, Date of birth, and Universal Attribute. The main area shows a table of search results for pseudonymized patients. The table has columns for CentraXX Patient ID, Last name, First name, Date of birth, and Organization unit. The data is filtered to show patients with the last name 'pseudonymisiert'.

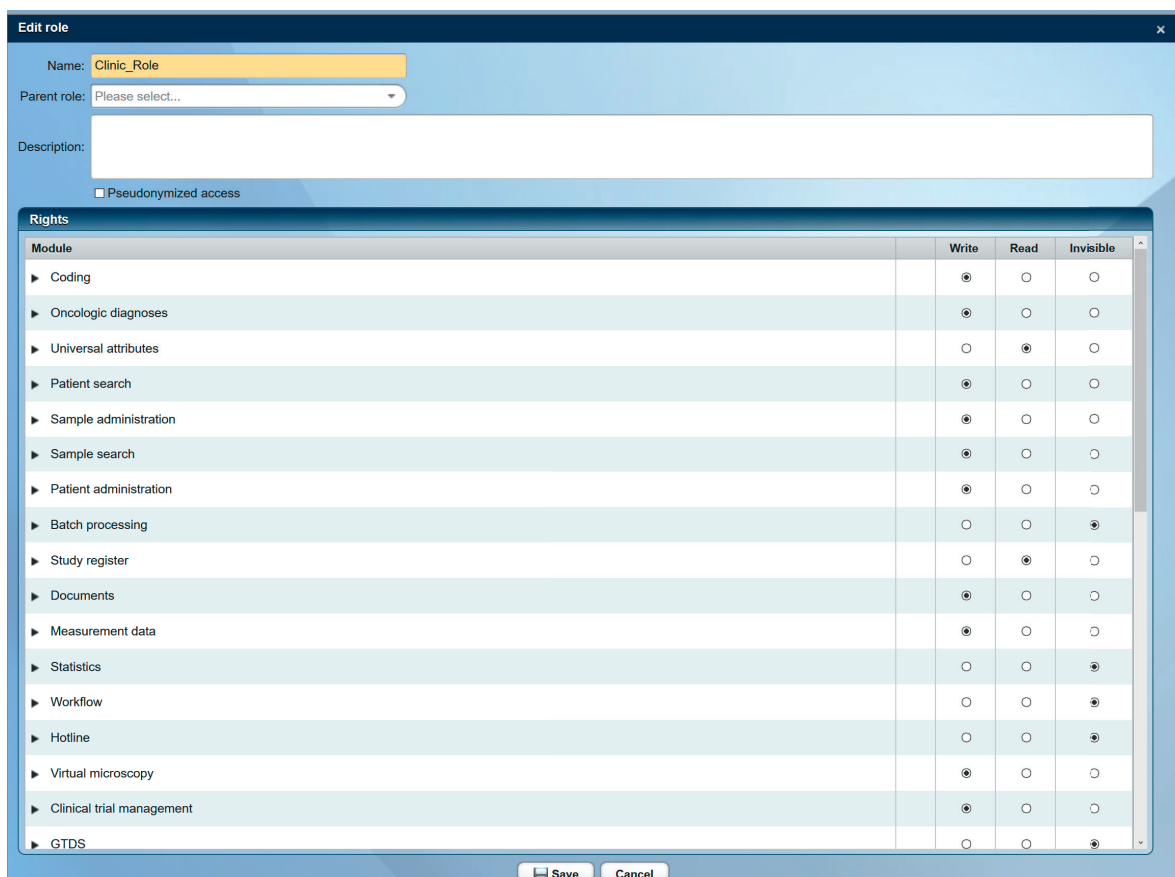
CentraXX Patient ID	Last name	First name	Date of birth	Organization unit
6253268056435153532	<pseudonymisiert>	<pseudonymisiert>	01/01/1939	Munich ONCOLOGY
6236207185940854466	<pseudonymisiert>	<pseudonymisiert>	01/01/1946	Munich ONCOLOGY
6134704326641642672	<pseudonymisiert>	<pseudonymisiert>	01/01/1950	Munich ONCOLOGY
7416110461944395093	<pseudonymisiert>	<pseudonymisiert>	01/01/1940	Munich ONCOLOGY
7842230753829428830	<pseudonymisiert>	<pseudonymisiert>	01/01/1975	Munich ONCOLOGY
670501652959751323	<pseudonymisiert>	<pseudonymisiert>	01/01/1950	Munich ONCOLOGY
8149030049971187844	<pseudonymisiert>	<pseudonymisiert>	01/01/1955	Munich ONCOLOGY
644243669220466272	<pseudonymisiert>	<pseudonymisiert>	01/01/1942	Munich ONCOLOGY
7394277400949219700	<pseudonymisiert>	<pseudonymisiert>	01/01/1933	Munich ONCOLOGY
6767647937198648660	<pseudonymisiert>	<pseudonymisiert>	01/01/1953	Munich ONCOLOGY
5142449984452944894	<pseudonymisiert>	<pseudonymisiert>	01/01/1938	Munich ONCOLOGY
7024388351757890118	<pseudonymisiert>	<pseudonymisiert>	01/01/1952	Munich ONCOLOGY
8846527605976594915	<pseudonymisiert>	<pseudonymisiert>	01/01/2012	CARD Biobank HNO
545237197733923813	<pseudonymisiert>	<pseudonymisiert>	01/01/2012	CARD Biobank HNO
4662118697520817739	<pseudonymisiert>	<pseudonymisiert>	01/01/2012	CARD Biobank HNO
6720969536447224348	<pseudonymisiert>	<pseudonymisiert>	01/01/2012	CARD Biobank HNO
6776264706346146545	<pseudonymisiert>	<pseudonymisiert>		HTA HNO
6277918934807690671	<pseudonymisiert>	<pseudonymisiert>	01/01/2006	TPL HNO
635673567519940094	<pseudonymisiert>	<pseudonymisiert>	01/01/1999	REACCH OUT BBOP
7332851270915594448	<pseudonymisiert>	<pseudonymisiert>	01/01/2016	HNO PPZU
8343316630794233284	<pseudonymisiert>	<pseudonymisiert>	01/01/2016	HNO PPZU
904438088300123194	<pseudonymisiert>	<pseudonymisiert>	01/01/1976	Cancer Biobank HNO

View of patient search for users with pseudonymized access

Rights/Roles Concept

CentraXX users are designated a specific role for each organizational unit they are assigned to, which defines their access rights for the organizational unit in question. Using the rights and role management in Cen-

traXX, the specific read and write access of a user can be determined in fine detail. It is also possible to completely remove entire modules or functions from the user's view.



Edit role

Name:

Parent role:

Description:

☐ Pseudonymized access

Module	Write	Read	Invisible
▶ Coding	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>
▶ Oncologic diagnoses	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>
▶ Universal attributes	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>
▶ Patient search	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>
▶ Sample administration	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>
▶ Sample search	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>
▶ Patient administration	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>
▶ Batch processing	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>
▶ Study register	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>
▶ Documents	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>
▶ Measurement data	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>
▶ Statistics	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>
▶ Workflow	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>
▶ Hotline	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>
▶ Virtual microscopy	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>
▶ Clinical trial management	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>
▶ GTDS	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>

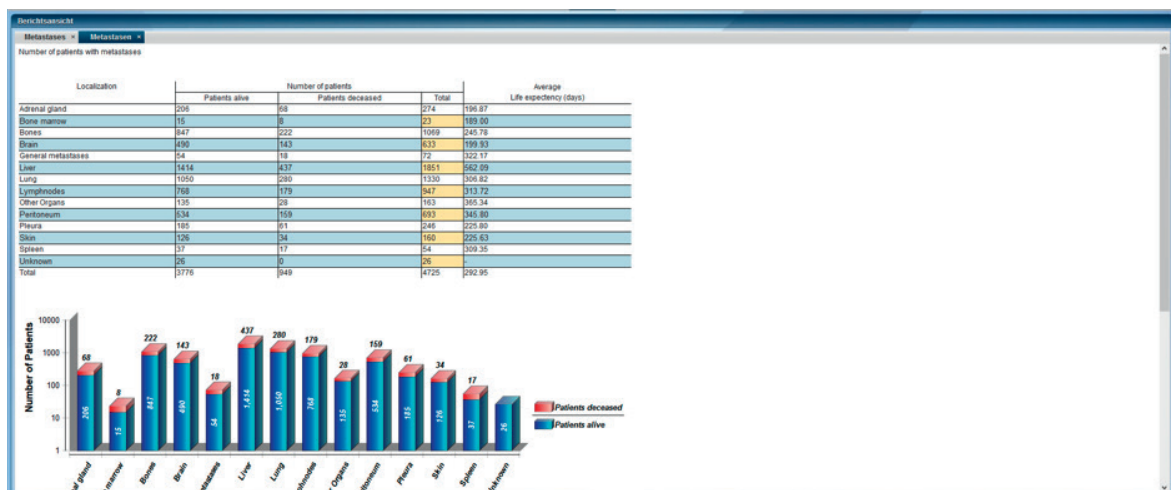
A role that summarizes all the rights of a user within an organizational unit

THE CENTRAXX[®] – FUNCTION MODULES:

Reporting Engine

All data stored in CentraXX can be analyzed. To do this, CentraXX integrates BIRT. With BIRT templates, all data fields in CentraXX can be accessed, evaluated and graphically

displayed. These reports can be exported as XML or PDF files. Reports can also be created automatically to be sent to specified recipients at predefined time intervals.



Example of a report generated with BIRT

Extended Search/Elastic Search

In addition to the Basic Search, CentraXX also offers the Extended Search, based on the Elastic Search technology. This search server, which can be hosted separately and

connected to CentraXX, offers significantly higher performance and some advanced search functionalities not found in the Basic Search.

Extended Search (Study Search)

Search criteria
 Patient with Age: > 3 AND Patient with Age: < 10 AND Patient with Sex: female AND (Sample with Sample kind: DNA OR Sample with Sample kind: Whole Blood) AND (ICD Coding with ICD 10 Code: C* OR ICD Coding with ICD 10 Code: D*) AND (Measurement finding with Measurement profile: Clinical Chemistry (Enzymes, Electrolytes, Trece elements) AND Measurement value (finding) with Creatinine-kinase: > 150 AND Measurement finding with Finding date: from 02/01/2016 to 02/19/2019) AND Metastasis with Certainty: any

AND + [-]

Patient Age > 3

Patient Age < 10

Patient Sex equal female (FEMALE)

OR + [-]

Sample Sample kind equal DNA (DNA)

Sample Sample kind equal Whole Blood (BLD)

OR + [-]

ICD Coding ICD 10 Code equal C*

ICD Coding ICD 10 Code equal D*

AND + [-]

Measurement finding Measurement profile equal Clinical Chemistry (Enzymes, Electrolytes, Trece e

Measurement value (finding) Creatinine-kinase (2157-6) > 150

Measurement finding Finding date from: 02/01/2016 to: 02/19/2019

Metastasis Certainty any

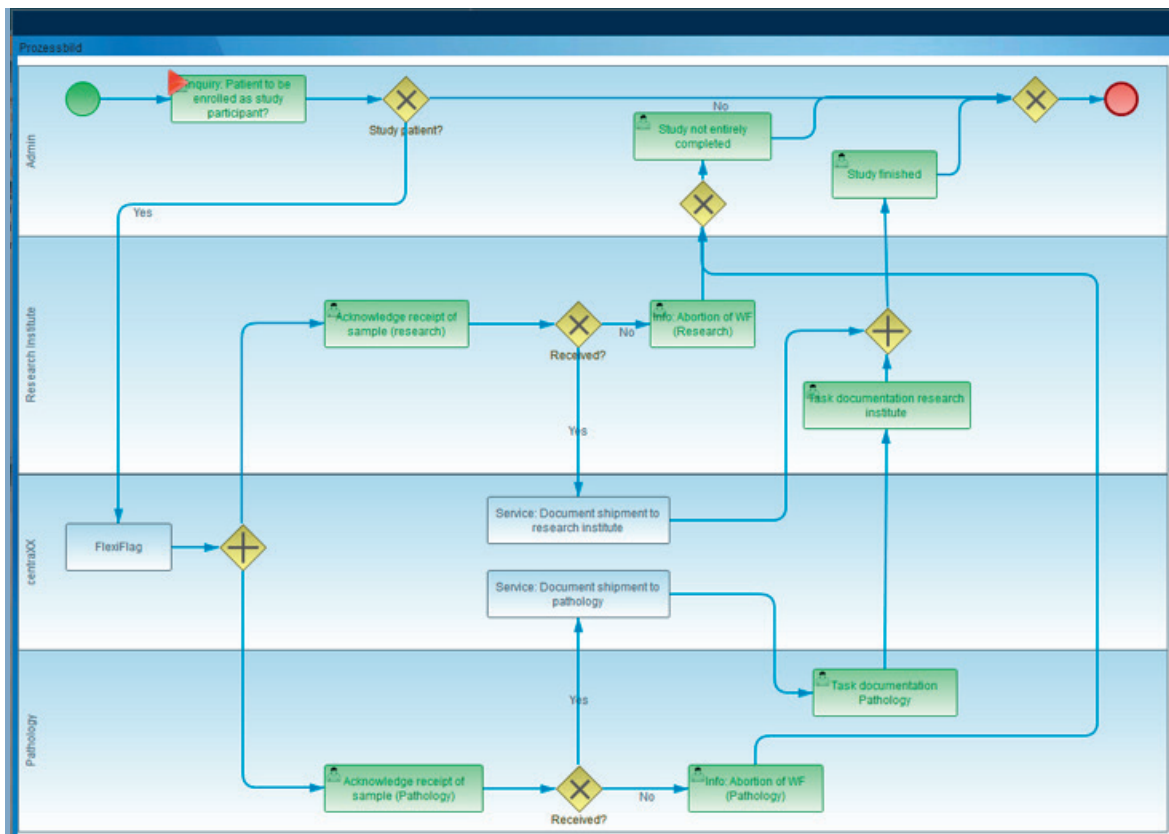
Search Load request... Save request... Close

Extended Search in CentraXX

Workflow Engine

The integrated Workflow Engine allows the creation of system-integrated processes in CentraXX using flexibly designed documentation masks with defined rules. With this tool, SOPs can be modelled into CentraXX to make data collection more efficient, more transparent and less prone to error. Certain work steps can be created parallel to each other in the Workflow Engine. All logics (e.g. validation, branching, etc.) can be implemented in the Workflow

Engine. A CentraXX workflow can be used anywhere in the system, be it in the Bio or the Trial module, to implement internal processes in a strategic and completely systematized manner. This means that all processes in the laboratory or in the Trial Unit can be handled according to tailor-made guidelines. The Workflow Engine is based on jBPM technology.

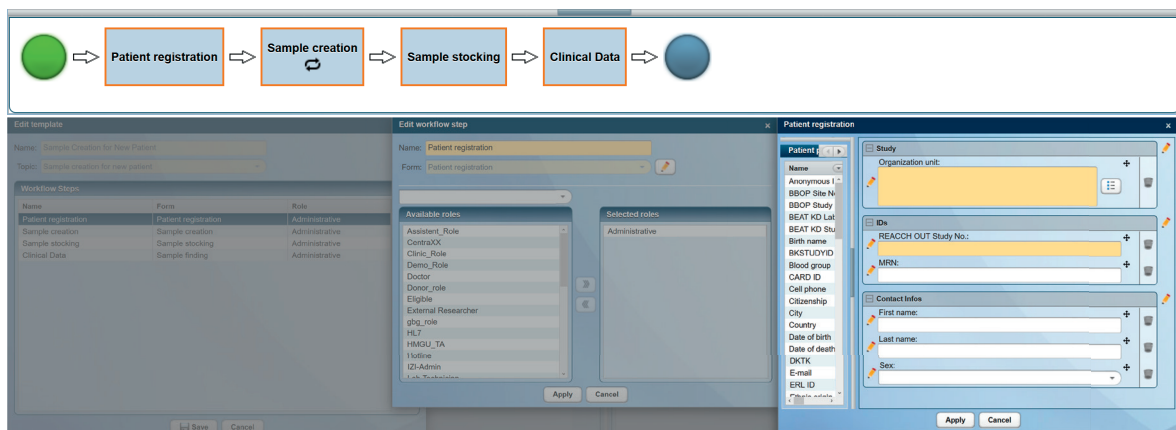


A Workflow Diagram in CentraXX

Workflow Designer

If the internal programmer resources are limited, the CentraXX Workflow Designer can be used. With drag & drop functions, this designer allows users to easily assemble

their own processes using CentraXX standard masks along with forms they have designed themselves with the forms designer.



The Workflow Designer for creating individual workflows

THE CENTRAXX[®] –PRODUCT FAMILY

- > **CentraXX Bio (Biobank System)**
- > **CentraXX Trial (Clinical Trial Management System)**
- > **CentraXX Ticket System**
- > **CentraXX Hotline**
- > **CentraXX MDR (Meta Data Repository)**
- > **CentraXX RDA (Raw Data Archive)**
- > **CentraXX Patient-App**
- > **CentraXX BoXX**

The CentraXX product family comprises of modules and functional elements that extend the core CentraXX Basis system according to different needs, as well as some modules that – technically speaking – could also be used as independent products (CentraXX MDR, CentraXX RDA). This collection of individual modules and functional elements allows CentraXX to provide users with longterm, tailor-made system solutions that can be continually expanded or adapted to meet increasing user requirements. The broad scope of CentraXX products also has

important practical implications for the future, helping establish data integration centers to create the technical and organizational prerequisites for exchanging data across locations and between clinical and biomedical research.

In addition, CentraXX has a comprehensive and flexibly expandable interface structure. CentraXX is currently equipped with the HL7 interface standards and supports IHE and XML.

CURRENT CENTRAXX® – INTERFACES (EXCERPT)

> Export/Im- port-Interfaces (CXX-XML)	> CentraXX/ CentraXX Sync. (CXX-CXX)	> PIX v3	> Liconic
> GTDS-Interface (CXX-HLP)	> Data Trustees (CXX-THS)	> ATNA	> Flatbed- Scanner 2D (CXX-CSA)
> HL7-Interface (CXX-HL7)	> Transfer Inter- face (CXX-TRA)	> ODM CDISC (CXX-ODM)	> Fluidx
> ADT	> Quantification (CXX-QUANT)	> Liquid-Han- dling-Platform (CXX-LHP)	> Micronic
> MDM	> IHE-Interfaces (CXX-IHE)	> Hamilton	> Thermofisher
> ORU	> XDS	> Tecan	> Ziath
> ORM	> PIX	> Ultra-Deep- Freeze- Warehouse (CXX-UTL)	> Virtual Microscopy
> DFT			> VMscope
> BAR			> Text Mining
			> Averbis

In addition to the REST interface, the system also offers a trustee interface (CXX-THS) and the CentraXX-CentraXX interface (CXXCXX), which establishes the connection between the „Treatment CentraXX“ on the one hand and the „Research CentraXX“ on the other. Further interfaces to liquid handling platforms, ultra-deep-freeze warehouses and scanners are available. CentraXX uses the latest Java and Framework technology with open source frameworks such as „Vaadin“ or „Spring“ and can also be operated in the cloud. Designed as a web-based solution, every authorized user has access to the latest data and development status of the system, regardless of location

and in either language (German/English). Combined with the integrated modules „Raw Data Archive (RDA)“ and „Meta Data Repository (MDR)“, CentraXX offers the comprehensive and necessary IT solution for personalized medicine. The integrated Workflow Engine offers additional support by orchestrating and optimizing even the most individual work processes. On the one hand, this helps avoid errors due to inadequate or forgotten work steps within the scope of study documentation or sample processing. On the other hand, this accelerates all documentation steps, displays them transparently, and makes them auditable.

KAIROS GmbH – an IQVIA business
Universitätsstraße 136
44799 Bochum

T +49 (0)234 / 58 88 21-0
M info@kairos.de
www.kairos.de

KAIROS GmbH – an IQVIA business
Reinhardtstr. 33
10117 Berlin

T +49 (0) 30 / 55 57 199-90
M info@kairos.de
www.kairos.de

KAIROS US / Boston
Office 05-111
200 Portland St
Boston, MA 02114
T +1 (857) 336-6730
M info@kairos.us
www.kairos.us