



ClinResearch

Institute for Monitoring . Data Management . Biometrics and Medical Writing

Electronic Data Capture
Interactive Web Randomization
Drug Supplies Management

PerChance | Study XX-0005

File Monitoring Users Help

New Open Save Delete Logout

Studies Study Setup Lists Randomization

General Treatments Design Settings

Name: Study XX-0005
 Description: PerChance GmbH, Germany

Date: 2010-04-21 09:02:58.0

Active design: PER (4:0)
 Active subject: Subject 1 on site 1001

General settings:

- RANDOMIZATION** real-time randomization; ad-hoc
- FACTORS** stratification factors
- FIXED RANDOM LIST** use a fixed random list
- NUMBER GROUPS** number groups, e.g. random
- SITES** the subjects will be randomized on two or more
- NUMBER OF SUBJECTS** the expected number of s
- KIT NUMBERS** medication kit numbers
- BLINDED** blinded design
 - single
 - double

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CDASH - Windows Internet Explorer

https://edc.clinresearch.com/ctrl38/handler/main/workkeyId=107742%3A12403c77767%3A-78-6&java_enabled=1&browser_name=1&browser=

Welcome, Dr. Geueke (Investigator + Signature - Test mode)

Martin Geueke

Pat.No. Birth Date Frozen Signed Verified

9006 10.03.60

Visit1 Visit2 Visit3 CH AE Signature

9006, Martin Geueke Instance 1 / 1

Demographics

- Inclusion Criteria
- Exclusion Criteria
- Smoking History and Alcohol Consumption
- Vitals Signs
- Central Laboratory Results
- Local Laboratory Results
- Medical History
- Physical Examination
- ECO-Test Results

Date of Visit

Date: 01 March 2009 (DD, MMM, YYYY)

Demographics

Date of Birth: 10 March 1960 (DD, MMM, YYYY)

Sex:

- Male
- Female
- Unknown
- Intersex

Race of subject:

- American Indian or Alaska Native
- Asian
- Black or African American
- Native Hawaiian or Other Pacific Islander
- White
- Other, please specify: _____

Filter: _____

Pat.No.: _____

Birth Date: _____

Apply RegExp Clear ?

Scr.No.	Pat.Id	Random	Birth Date	Randomdate
11805	1806	YES	03.53	10.02.2009
11806	1807	YES	03.53	10.02.2009
11807	1808	YES	01.41	10.02.2009
11808	1809	NO	02.28	
11809	1810	NO	02.36	
11810	1809	YES	02.36	10.02.2009
11811	1810	NO	02.30	
11812	1810	NO	10.30	
11813	1810	YES	06.29	10.02.2009

Screening Randomization

Randomization

Weight: 80 kg = 176.00 pound

Date of first infusion: 11 January 2009 (day, month, year)

To randomize the patient, please save the current page and then click here: [Click here](#)

Only for the pharmacist:

Infusion will be prepared for treatment; system sends a notification e-mail

Get the prescription from the following report

Filter: _____

Scr.No.: _____

Pat.Id.: _____

Apply RegExp Clear ?

Site ID: 999916 Tue Apr 20 12:03:27 CEST 2010

Site data:

Investigator: Dr. Jan Wuertner

Site phone: --

Mobile phone: --

Site fax: --

E-Mail: wuertner@clnr.de

Drug delivery address: ClinResearch GmbH
 Robert-Perthel-Straße 77a
 50739 Köln
 Germany

Assemble orders Pending shipments (0)

KIT ID	Status	Target shipment
1 80391	<input checked="" type="radio"/> <input type="radio"/> damaged <input type="radio"/> unavailable	Select shipment
2 80392	<input checked="" type="radio"/> <input type="radio"/> damaged <input type="radio"/> unavailable	Select shipment
3 80393	<input checked="" type="radio"/> <input type="radio"/> damaged <input type="radio"/> unavailable	Select shipment
4 80394	<input checked="" type="radio"/> <input type="radio"/> damaged <input type="radio"/> unavailable	Select shipment
5 80400	<input checked="" type="radio"/> <input type="radio"/> damaged <input type="radio"/> unavailable	Select shipment
6 80402	<input checked="" type="radio"/> <input type="radio"/> damaged <input type="radio"/> unavailable	Select shipment

ASSESSMENT OF SHIPMENTS

Shipment ID	Shipment Date, Service	Tracking ID	Assessment	Temperature	Comment
80000502	18-12-2009, DHL	9944	<input checked="" type="radio"/> within range <input type="radio"/> out of range <input type="radio"/> lost	2.3	ok
80000544	04-01-2010, TNT		<input checked="" type="radio"/> within range <input type="radio"/> out of range <input type="radio"/> lost	3.1	

all kits to new shipment

Save Save changes!

Electronic Data Capture with iCRF and interactive web randomization

In 1999 **ClinResearch** was founded as a full service provider for clinical studies phase II to IV and post marketing surveillances.

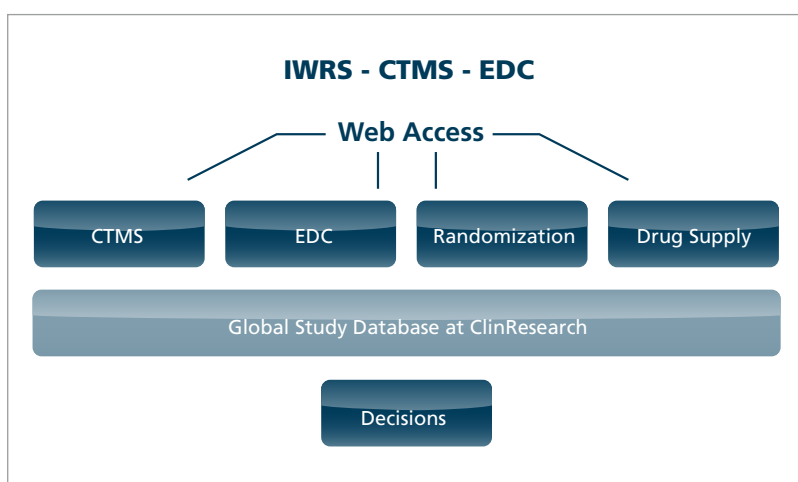
ClinResearch is located in Cologne, Germany (headquarter) and has subsidiaries in Moscow (Russia), Kiev (Ukraine), San Diego (USA) and Sydney (Australia).

ClinResearch is the CRO with the most experience worldwide in the planning and conduction of adaptive designed clinical trials.



ClinResearch Services include:

- Study set-up activities (incl. study protocol and case report form development, regulatory affairs)
- Project Management and Monitoring
- Data Management
- Auditing
- Statistical evaluation and Statistical consulting
- Report writing
- Drug safety

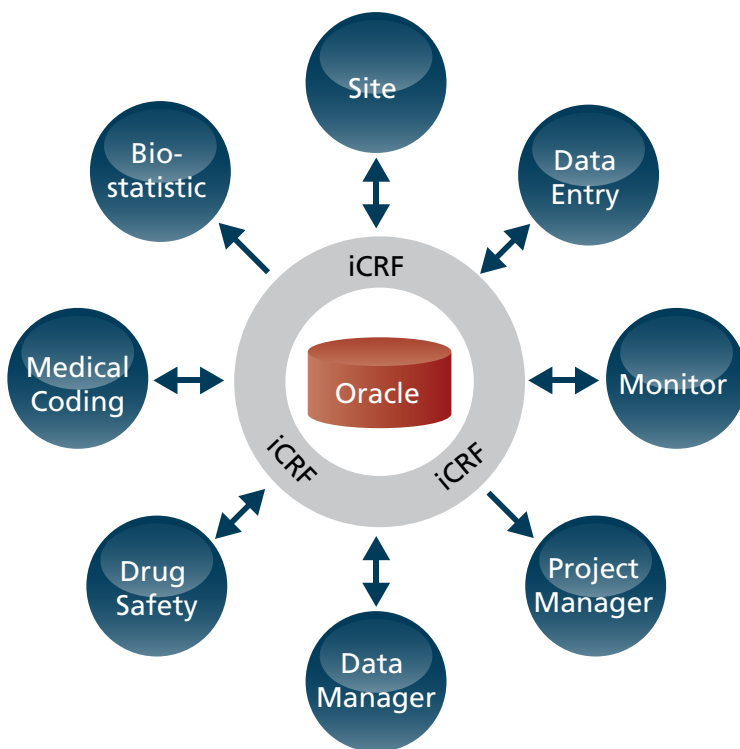


ClinResearch has developed web based systems for electronic data capture and interactive web randomization using the latest technical standards in database technology and internet programming.

Our EDC/IWRS systems were specifically designed to support trials with adaptive interim analyses, including management of clinical drug supplies.

iCRF Basics

- EDC studies
 - Hybrid studies
 - Multi-language support
 - Flexible role based rights management
 - Thin client, zero footprint
 - Edit checks (online)
 - External edit checks (offline)
 - Medical coding
 - Data query management
 - Reporting (HTML, PDF)
- Clinical Data Management System (CDMS)



iCRF Features

- AE / SAE notification via e-mail
- Event triggered e-mails
- Translation of free text entries
- Expert assessments (e.g. subject enrolment)
- Defining new rights and roles (fine grained rights management)
- Electronic signature
- Picture upload

iCRF Technical key features

- Web based system with three tiers:
 - Database backend: Oracle 10g
 - Application server: Apache and Tomcat Cluster
 - Browser client: Internet Explorer or Firefox
- Highly flexible through modular architecture with defined interfaces
- State of the art database system: Oracle 10g

iCRF Validation and documentation according to GAMP 5 and 21 CFR Part 11

- User requirements
- Functional specification
- Design specification
- Risk assessment
- Test plan
- Test logs
- Release certificates
- Integrated traceability

Advantages of EDC vs. Paper

- Improved data quality
- Faster access to results
- Only one location for data storage
- Only one unique process for data
- Customized reports for PM/Client
- Implementation of protocol amendments
- Smooth data cleaning process

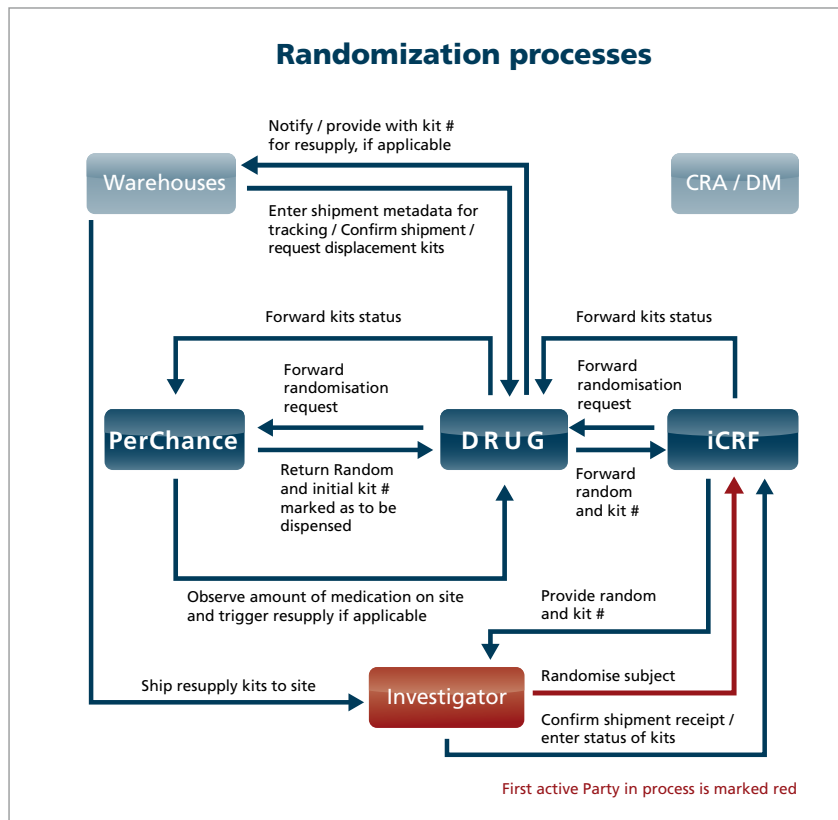
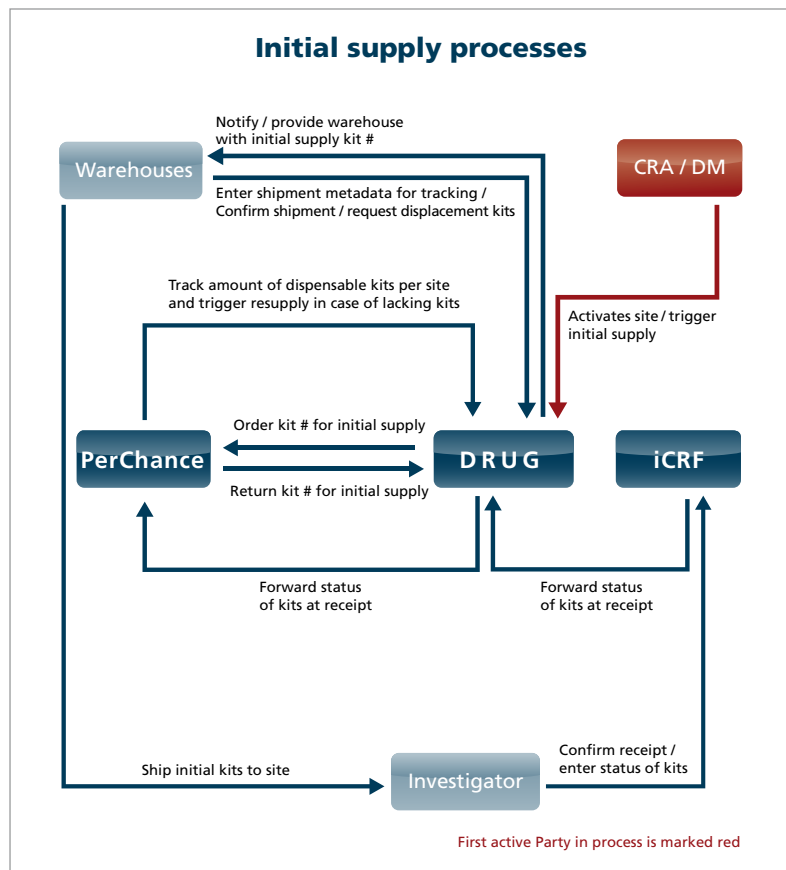
DRUG - Drug supply and Randomization Utility Group

This tool provides all drug supply management functionalities.

These include management and tracking of medication kits, monitoring of related workflows and notification of assigned staff for defined process milestones.

The tool provides all interfaces to **PerChance** utilised for randomization & medication kit administration and unblinding purposes.

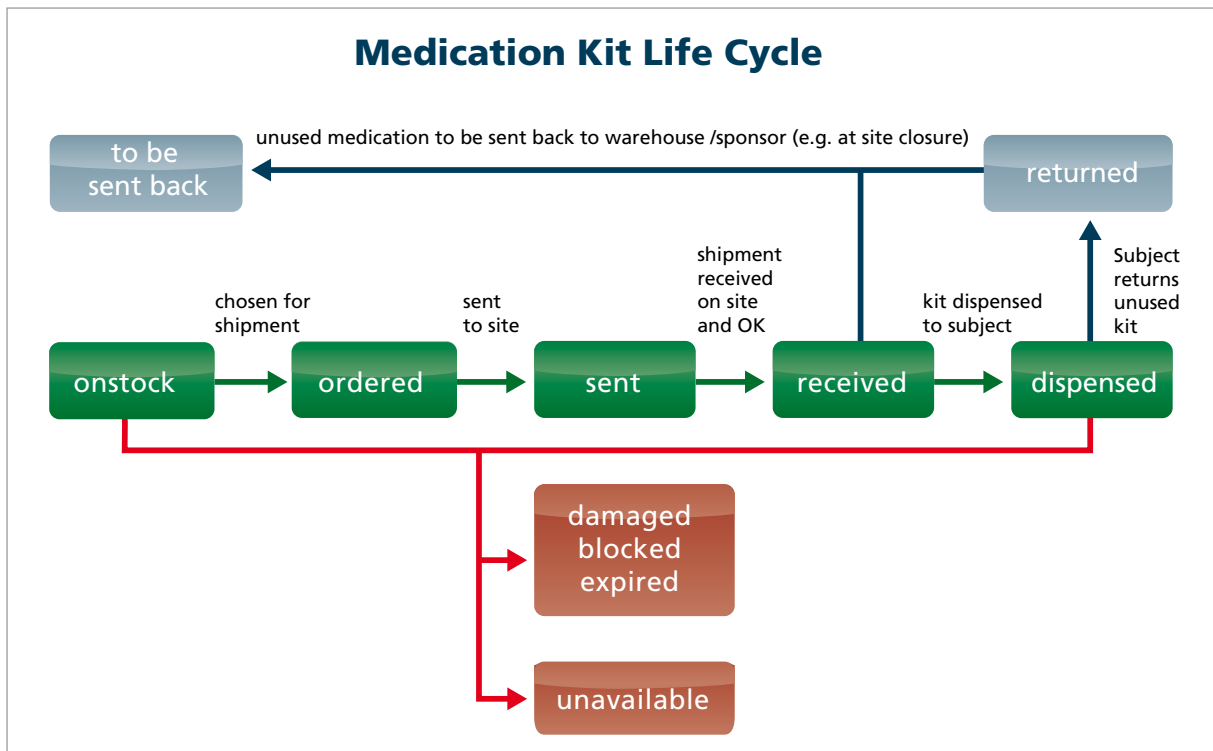
The consistent separation of **PerChance**, dealing with unblinded data (randomization list, mapping of medication kit and treatment group) and **DRUG** ensures that all involved staff is blinded throughout the entire study process.



When the investigator randomizes a subject to the study, he will request a randomization number and a kit number to be dispensed to the subject via the **iCRF**.

The **iCRF** forwards the request to **PerChance** via **DRUG**.

PerChance returns a randomization number as well as a kit number (of treatment available onsite and receipt of good condition confirmed) via the **iCRF**.



ClinResearch uses warehouses in Cologne, Moscow, and Kiev. Shipments within the EU are delivered within 2 days to site.

Shipment times Russia:

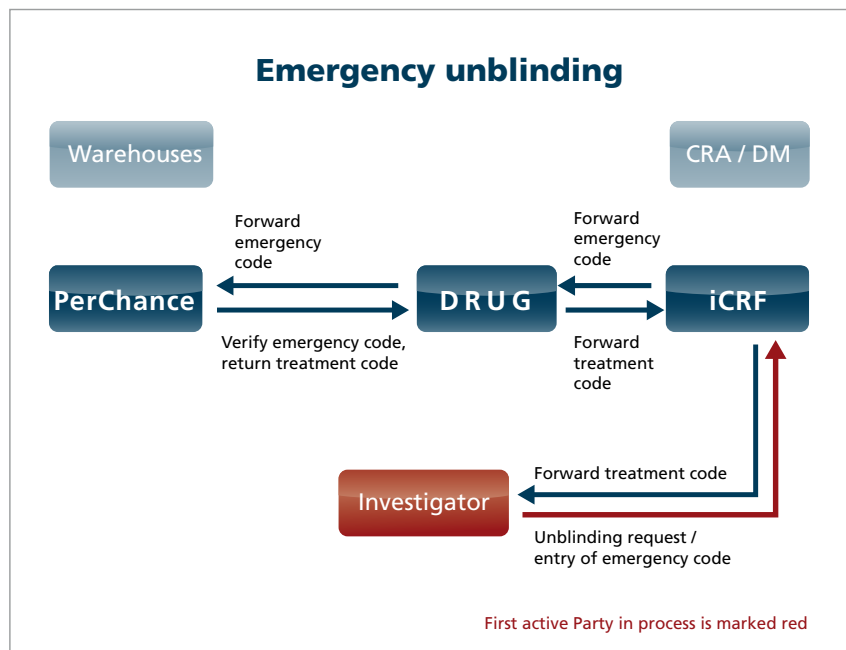
- Moscow 2 days
- St. Petersburg 3 days
- Siberia 3 - 4 days

Shipment times Ukraine:

- Kiev 1 day
- Regional site 2 days

In case of an emergency, the investigator has the ability to identify the treatment group of a subject via the **iCRF**.

The emergency code list is produced by **PerChance** and the sealed emergency code list is then distributed directly to the sites. Only the responsible site personnel has the potential authorization to unblind a subject.



ClinResearch Services

ClinResearch GmbH, since 1999

10 Years Experience with Adaptive Designs

Since its foundation in 1999 ClinResearch has been a key provider of adaptive trial services to the pharmaceutical, biotechnology, and medical service industries. To date ClinResearch has helped more than 20 customers to design and successfully complete over 80 adaptive clinical trials ranging from phase II to IV. With its headquarters in Cologne, Germany and affiliate offices located in Moscow, Russia and Kiev, Ukraine, ClinResearch provides Pan-European trial services, including Central and Eastern Europe.

Services in Biostatistics and Medical Writing

Our statistical services include consulting, statistical design, statistical analysis, and programming. Our experienced and dedicated team of statisticians can assist you with the set up of Data Monitoring Committees (DMC), organizing and executing statistical interim analyses including clinical reports, and may also service as an Independent Statistical Center (ISC). Our statistical experts practice a seamless co-operation with our medical writers ensuring accuracy and consistency of study data.

Services in Clinical Data Management

We develop web based systems for data capture and data cleaning, randomization, and drug supplies management. Our clinical data management professionals and IT specialists can help you manage your adaptive designed trial programs by providing the scale and flexibility of data services needed to tackle the challenges of timely and high quality interim data. We can support you with customized clinical database design, data management and validation plans, data cleaning services, medical coding and medical reconciliation, SAE reporting and related services.

We are working according to CDISC standards since 2006.

Services in Clinical Monitoring and Project Management

With comprehensive experience in managing clinical trials, our project managers, monitors and regulatory experts know what it takes to run an adaptive trial: Regulatory expertise, adaptive monitoring schedules, and flexible project management are part of our regular service offered.

All projects are managed by the same processes and SOPs, based on long term experience with designing and running adaptive designs in a variety of different therapeutic areas.

ClinResearch

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