



RERAND - RDC Extension for Randomisation

Problem

Almost any controlled trial requires randomisation of the subjects. In the past randomisation has been done through sequential paper lists and blind break envelopes. Interactive Voice Response Systems (IVRSs) have delivered a more timely and versatile, however, costly solution for randomisation through telephone. With the widespread usage of Internet Interactive Web Response Systems (IWRS) are replacing the bulky IVRS systems. Both, IVRS and IWRS require entering the data twice in the IxRS system and the (e)CRF and a reconciliation between the IxRS system and the (e)CRF. In case of an eCRF the IWRS and the eCRF which are both web based systems can be integrated into a single system reducing data entry by 50% and making reconciliation superfluous. This results in significant cost savings.

Solution

RERAND is a software package to be added on top of RDC delivering an IWRS style randomisation fully integrated into RDC.

- The validated Oracle Clinical randomisation functionality is used as backbone
 - Any type of permuted-block randomisation is possible in OC
 - Randomisations can be performed out of OC and loaded into OC
- By convention randomisation is possible in test mode and in production mode
 - The derivation procedures that do the randomisation using **RERAND** can be thoroughly tested for every study in test mode before activating them
- Randomisation in RDC happens as in any IWRS system
 - The investigator enrolls the subject
 - The subject's data required for stratification are entered
 - **RERAND** randomises the subject and displays the treatment number
- Randomisations can be communicated through email, this requires an RDC email system like **REMAIL**
- Further functionality requires RDC links like **RELOPO** for integration into RDC to provide role specific access
 - Blind breaks for investigators to avoid randomisation envelopes
 - Maintenance and communication of the clinical sites' drug supply status (which kits are on-shelf in a site) to assure enough stock at the clinical sites
 - Write access to the drug supplier
 - Read access to others involved in the trial



Example data required for randomisation

Study: [REDACTED]	Visit Date: [REDACTED]	Patient: 1003
Visit: RANDOMIZATION		
Comply with criteria	<input type="checkbox"/> Yes <input type="checkbox"/> No	
Criteria which were not met	<input type="text"/>	
Please check Yes and Save		
Ready for randomization	<input type="checkbox"/> Yes <input type="checkbox"/> No	
Reasons that prevent the randomization	<input type="text"/>	
Randomization number	<input type="text"/>	
Randomization date	<input type="text"/>	Randomization time <input type="text"/>
Remember when last randomization email was sent	<input type="text"/>	

Confirm data and request randomisation

Study: [REDACTED]	Visit Date: 05-06-2011	Patient: 1003
Visit: RANDOMIZATION		
Comply with criteria	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	
Criteria which were not met	<input type="text"/>	
Please check Yes and Save		
Ready for randomization	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	
Reasons that prevent the randomization	<input type="text"/>	
Randomization number	<input type="text"/>	
Randomization date	<input type="text"/>	Randomization time <input type="text"/>
Remember when last randomization email was sent	<input type="text"/>	



Unmet inclusion criteria can prevent randomisation

Study: [REDACTED]	Visit Date: 05-06-2011	Patient: 1003
Visit: RANDOMIZATION		

Comply with criteria Yes No

Criteria which were not met

Please check Yes and Save

Ready for randomization Yes No

Reasons that prevent the randomization

Inclusion Criteria Baseline not all YES.

Randomization number

Randomization date Randomization time

Remember when last randomization email was sent

Randomisation has been performed after corrections

Study: [REDACTED]	Visit Date: 05-06-2011	Patient: 1003
Visit: RANDOMIZATION		

Comply with criteria Yes No

Criteria which were not met

Please check Yes and Save

Ready for randomization Yes No

Reasons that prevent the randomization

Randomization number

Randomization date Randomization time

Remember when last randomization email was sent



Offer

RERAND comes as software package with full software development life cycle documentation:

- User requirements
- Design specification
- Module build and test
- System Test
- User Acceptance Test
- User Manual
- System Manual

The user acceptance test can be customised to address specific customer settings.

Availability for RDC Versions

- RDC 4.5.3
- RDC 4.6.n

Pricing

- €500 per OC user, optional €250 for REMAIL and €250 for RELOPO
- €100 per OC user annual maintenance and support fee, optional €50 for REMAIL and €50 for RELOPO
- customisation and implementation on a time and material basis

For more information please contact:

Hauke Kindler – Reliable Lifesciences Consulting

Mobile: +49/171/786 76 95

Phone: +49/2131/450 957

Fax: +49/2131/450 958

E-mail: hauke.kindler@relico.de, URL: www.relico.de

Address: Am Jörne Meerke 47a, 41462 Neuss, Germany

