



T E N A L E A

TRANS EUROPEAN NETWORK FOR CLINICAL TRIALS SERVICES

TENALEA

A European Project for the Development and Deployment of a Validated Randomisation System

EFSPI workshop 'Adaptive Randomisation - Today and Tomorrow'

EORTC Data Center

7 December 2007

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T E N A L E A

TRANS EUROPEAN NETWORK FOR CLINICAL TRIALS SERVICES

TENALEA – the problem

- In one academic hospital 30 different ways of randomising a patient in a clinical trial
- Mixture of fax, phone, ivr and online
- Dozens of accounts, URL's and phone numbers
- Validation of systems used by Academics



What is TENALEA?

- Initiative involving academics and pharma
- Harmonisation of randomisation procedures
- Consortium main contractors:
 - Nederlands Kanker Instituut, NL (Coordinator)
 - Institut Gustave Roussy, FR
 - Cochrane Collaboration UK
 - Universitäts Klinikum Köln / KKSK, DE
 - Medical University of Gdansk, PL
 - ORGANON NV, NL
 - Réseau de Cancérologie d'Aquitaine, FR
 - *InferMed* Ltd, UK



TENALEA – formal contracts

- TENALEA Market validation 2004-2005
 - Market survey for need for a randomisation service
 - Service requirements of different target user groups
 - Service provisioning terms of use, price
- TENALEA Initial Deployment 2006-2010
 - Randomisation service & Remote Data Entry
 - Consortium of academics & Industry
 - 3.75M€ funding from eTEN programme of EU
 - UK, France, Germany, Poland and the Netherlands



T E N A L E A

TRANS EUROPEAN NETWORK FOR CLINICAL TRIALS SERVICES

ALEA Interoperability

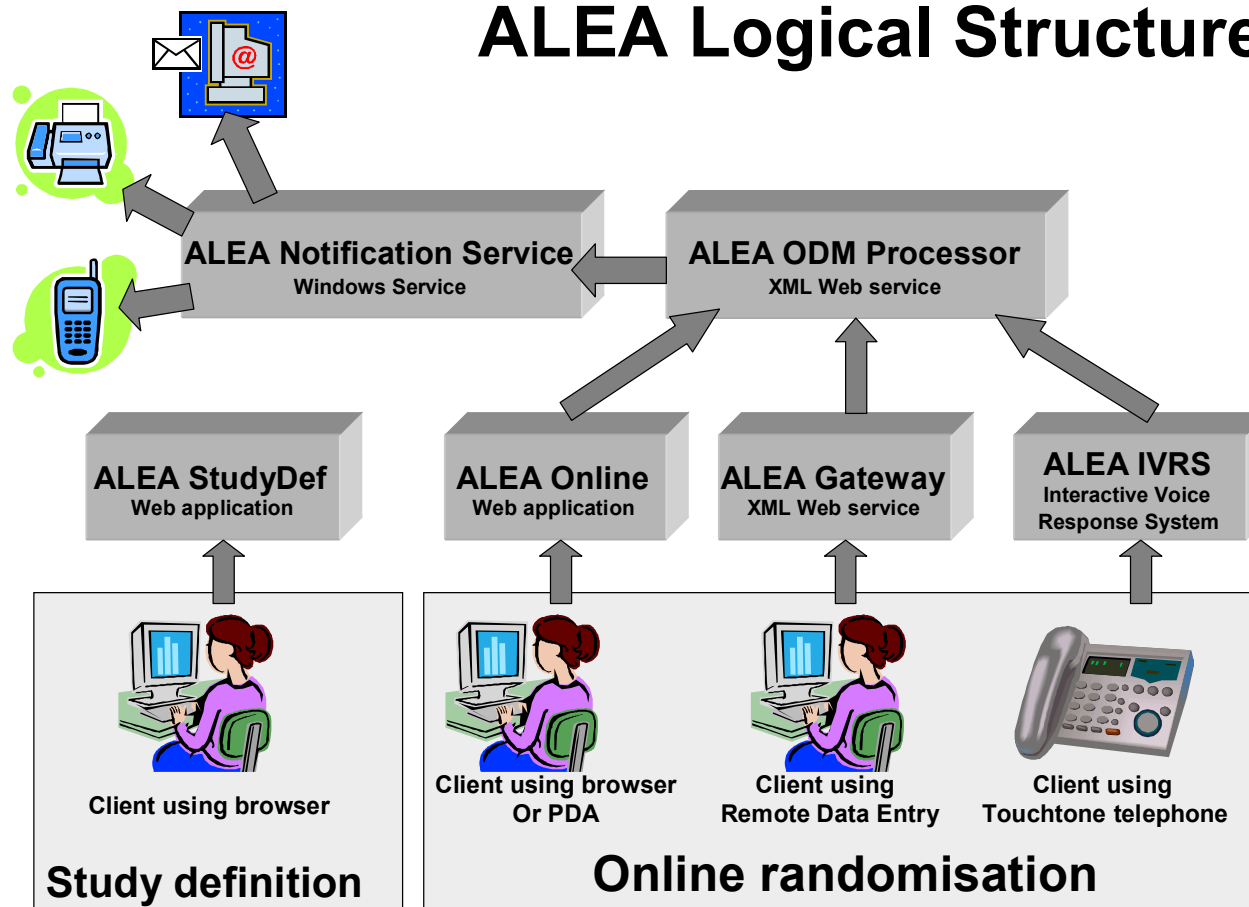
- Interoperability is key issue
- ALEA is CDISC ODM Based
- Implemented as XML Web service
- Includes gateway service for non-ODM compliant systems



T E N A L E A

TRANS EUROPEAN NETWORK FOR CLINICAL TRIALS SERVICES

ALEA Logical Structure

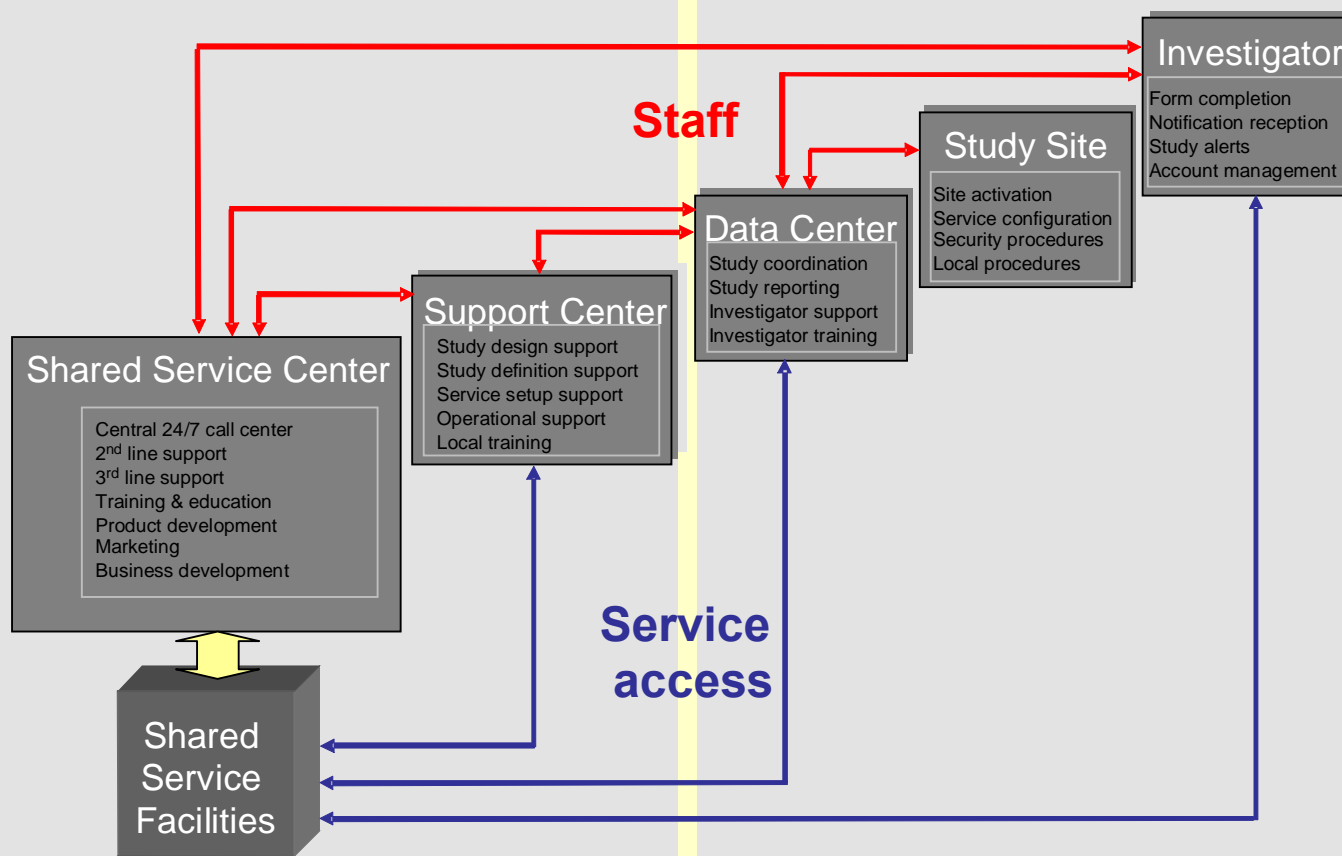




TENALEA Deployment organisation

Service providers

Service consumers





T E N A L E A
TRANS EUROPEAN NETWORK FOR CLINICAL TRIALS SERVICES

ALEA demonstration



- ALEA Randomisation program
 - Studies
 - Study definition
 - Create New Study
 - Open Studies
 - Pending Studies
 - TESTPE01**
 - Study Status
 - Study Numbering
 - Study Javascript library
 - Forms
 - Randomisations
 - Persons Involved
 - Institutes Involved
 - Export Data (all forms)
 - Import Data
 - Delete test data
 - MacroOptions
 - Reports
 - Study user permissions
 - Suspended Studies
 - Closed Studies
 - Address Book
 - Content Management
 - Personal Settings
 - System administration
 - Online Help



Edit general study data

Complete general study information and press save study to create or update the study info

StudyVersion: 1, Activation date: Pending, Setup date: 29-03-2006, Date closed:

Local study code

Study short

Long study title

Description

Close on fixed date Date to close

Close on fixed accrual Number of patients

EMA Study ID

Study scope

Study phase

Default Language

- Enabled Languages
- French
 - Dutch
 - Italian
 - Polish
 - Spanish
 - Portuguese
 - German

Enable long IVR answer confirmations

Enable MACRO

MACRO Proxy Service Address

?

ALEA Randomisation program

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 - Create new randomisation
 - RT vs No RT
 - Treatments
 - New Treatment
 - RT
 - No RT
 - High dose vs low dose
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 - Institutes Involved
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Edit study randomisation

Randomisation name T

Randomisation method

Blocksize factor

Coin bias factor

Biased coin threshold

blind randomisation

Relevance expression script

- Biased Coin**
- Minimisation
- Block Method
- Random Block Method
- List
- Manual
- Adapted minimisation
- Custom Pocock

Pocock D Script

```
function D(int[] treatmentsinstratum,  
          int[] trt_ids,  
          int strata_q_id)  
{  
}
```

Pocock Gk Script

```
function Gk(int[] strataimbalance, int[] strata_q_ids)  
{  
}
```

Pocock Pk Script

```
function Pk(k,n)  
{  
  // k: the rank of the treatment  
  // n: the number of treatments  
}
```

- Content Management
- Personal Settings
- System administration
- Language Settings

Save randomisation

Delete randomisation



//n: the number of treatments

}

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Edit treatments in randomisations

Treatment name T

Treatment description T

Treatment active

Treatment weight

Treatment export code

Treatment relevance expression

?

ALEA Randomisation program

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 - RT vs No RT
 - Treatments
 - New Treatment
 - RT
 - No RT
 - High dose vs low dose
 - Treatments
 - New Treatment
 - High dose
 - Low dose
 - Stocks overview
 - Stocks overview
 - ANTONI VAN LEEUWENHO
 - Create Shipment
 - Shipment: B920332
- Persons Involved
- Institutes Involved
- Export Data (all forms)
- Import Data
- Delete test data



Manage shipment

Study=TESTPE01,Randomisation=High dose vs low dose,Institute=ANTONI VAN LEEUWENHOEK ZIEKENHUIS,shipment=1

Shipment status=Received
 Shipment created at:07/12/2006 00:05:58
 Shipment sent to institute at:01/12/2006 00:00:00
 Shipment received by institute at:02/12/2006 00:00:00

Edit shipment status

Enter date the shipment was invalidated ?

Edit box list

ALEA Box id	Box id	Treatment	Batch code	Expiry date	Box status	patient number	Hand over date	Commands
1	1	High dose	CBP3943	01/01/2010	Available			Edit
2	2	High dose	CBP3943	01/01/2010	Available			Edit
3	3	Low dose	CBP3943	01/01/2010	Available			Edit
4	4	High dose	CBP3943	01/01/2010	Available			Edit
5	5	Low dose	CBP3943	01/01/2010	Available			Edit
6	6	High dose	CBP3943	01/01/2010	Available			Edit
7	7	Low dose	CBP3943	01/01/2010	Available			Edit
8	8	High dose	CBP3943	01/01/2010	Available			Edit
9	9	High dose	CBP3943	01/01/2010	Available			Edit
10	10	Low dose	CBP3943	01/01/2010	Available			Edit
11	11	Low dose	CBP3943	01/01/2010	Available			Edit

ALEA Randomisation program

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 - Forms
 - Create Form
 - Randomisation form
 - Notifications
 - Questions
 - Create new question
 - GENDER (Gender of the pa
 - PRIORTRT (Did the patien
 - RTVSNORT (Randomisatio
 - Test form entry
 - Generate test forms
 - Delete test data
 - Form Permissions
 - Export Data
 - Generate validation script
 - Second randomisation form
 - Randomisations
 - Create new randomisation
 - RT vs No RT
 - High dose vs low dose
 - Persons Involved
 - Institutes Involved
 - Export Data (all forms)
 - Import Data
 - Delete test data



ALEA

Software for randomisation in clinical trials

Edit form question

Edit question properties and click question save to save the changes

Question code Question active

Question name T

Question description T

Question type

Stratification factor
Stratify to:
 RT vs No RT
 High dose vs low dose

Question mandatory

Print on confirmations Include in data export

Error message T

Calculation

Relevance expression script

?

ALEA Randomisation program

- Studies
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 - TESTPE01
 - Study Status
 - Study Numbering
 - Study Javascript library
 - Forms
 - Create Form
 - Randomisation form
 - Notifications
 - Questions
 - Create new question
 - GENDER (Gender of the patient)
 - yes
 - no
 - PRIORTRT (Did the patient receive prior randomisation?)
 - RTVSNORT (Randomisation stratification)
 - Test form entry
 - Generate test forms
 - Delete test data
 - Form Permissions
 - Export Data
 - Generate validation script
 - Second randomisation form
 - Randomisations
 - Create new randomisation
 - RT vs No RT
 - High dose vs low dose
 - Persons Involved
 - Institutes Involved
 - Export Data (all forms)



ALEA

Software for randomisation in clinical trials

Edit question categories

Category text

Range minimum (inclusive) Range maximum (exclusive)

Category code

Export code

Category eligible

- ALEA Randomisation program
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 - Study Javascript library
 - Forms
 - Create Form
 - Randomisation form
 - Notifications
 - Create new notification
 - N1
 - Questions
 - Create new question
 - GENDER (Gender of the patient)
 - yes
 - no
 - PRIORTRT (Did the patient receive prior randomisation?)
 - RTVSNORT (Randomisation status)
 - Test form entry
 - Generate test forms
 - Delete test data
 - Form Permissions
 - Export Data
 - Generate validation script
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Edit notifications

Notification name: Confirmation to clinician Notification active

Hide treatment on notification

Notification format: Letter with answer

Notification medium: Email

Notification template: standard

Will be sent to: Clinician (entering addr.)

Address reference: Enter

Title: @STUDY_TITLE

Subtitle: @STUDY_DESCRIPTION

Header text: Notification of the registration of a patient in TESTPE01

Registrationdate line: Patient registered at: @REG_DATE

Formdate line: Form completed at: @FORM_DATE

Opening line: Dear Dr @CLINICIAN,

Footer text: Thank you for entering a patient into the TESTPE01 study

use picklist to select entering clinicians for whom this notification should be sent

Relevance expression script:

Schedule notification

Schedule script:

Save notification Delete notification Edit mailing list ?

ALEA Randomisation program

- Studies
 - Open Studies
 - blindtest
 - blocktest
 - CAIRO2**
 - CTG
 - Data study
 - DRAIN
 - ELOSOL
 - EsoVUmc
 - Hepatica
 - IKL2003-02
 - M01BAX
 - M02STA
 - M04GTB
 - M06PRO
 - M99RAD
 - MATADOR
 - Mates/NVALT5
 - Mazorg
 - N03DFE
 - N04IRC
 - N04LFV
 - N04POM_H+X
 - N04POMn
 - N05ECP
 - N05GEA
 - N05HME-1
 - N05TSP
 - NVALT4
 - NVALT5
 - NVALT7
 - PARTIR
 - POPART
 - Raster
 - RELAPS
 - SIOP
 - Urologie

Clinician: Patient: Mode

user: System Administrator



CAIRO2 - Randomisation

| | |
|--|---|
| investigator/physician | <input type="text" value="Creemers, - Catharina ziekenhuis"/> |
| Institute | Catharina ziekenhuis |
| Site number | <input type="text" value="34387"/> |
| Name code | <input type="text" value="WS1"/> |
| Date of birth (dd/mm/yyyy) | <input type="text" value="01/04/1945"/> |
| Age | 61 |
| Gender | <input type="text" value="Male"/> |
| Prior adjuvant therapy? | <input type="text" value="1= yes"/> |
| Number of organs affected? | <input type="text" value="1 = 1 organ"/> |
| Serum LDH? | <input type="text" value="1 = normal"/> |
| Date written informed consent CAIRO2 main study (dd/mm/yyyy) | <input type="text" value="01/12/2006"/> |
| Does patient participate to additional bloodsampling for side studies? | <input type="text" value="1 = yes"/> |
| Date written informed consent for additional bloodsamples (dd/mm/yyyy) | <input type="text" value="01/12/2006"/> |
| Date of baseline Quality of Life (dd/mm/yyyy) | <input type="text" value="05/12/2006"/> |
| Is this patient eligible? | <input type="text" value="1 = yes"/> |
| <input type="button" value="Submit Form"/> | |

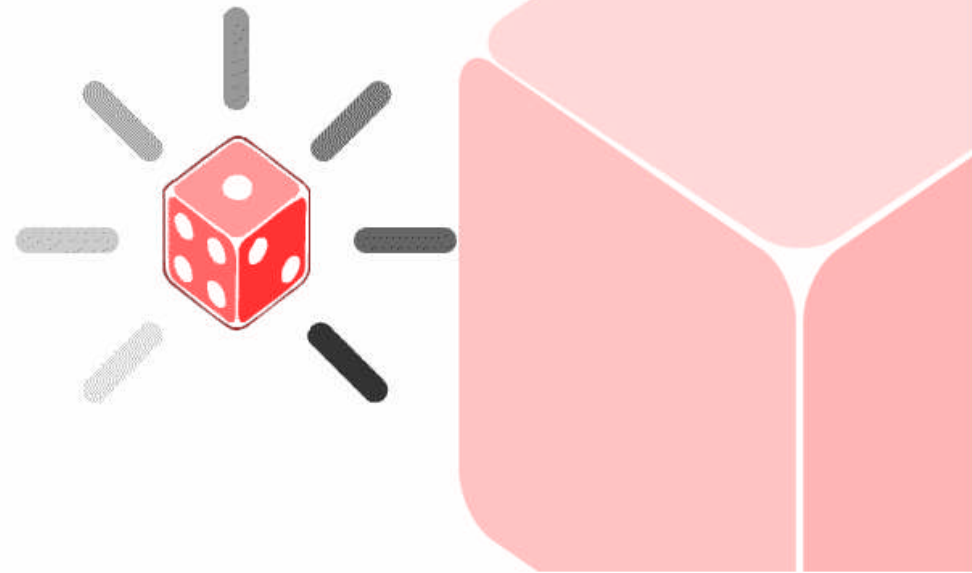
Clinician: Patient: Mode:

- ALEA Randomisation program
 - Studies
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 - Pending Studies
 - TESTPEO1**
 - Suspended Studies
 - Closed Studies
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 - Personal Settings
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Please wait while ALEA processes your request

Your request has been processing for 8 seconds





Nederlands Kanker Instituut
Antoni van Leeuwenhoek ziekenhuis
Raster Groep
Plesmanlaan 121
NL 1066 CX Amsterdam
The Netherlands
Tel. (+31 20) 5122317
Fax. (+31 20) 5122322

**Patient enrollment for study: Raster
Array prognostiek van borstkanker
Form: Pathology form**

Confirmation generated at: Wednesday, May 04, 2005
Registration date: Wednesday, May 04, 2005

Dr. [REDACTED]
ANTONI VAN LEEUWENHOEK ZIEKENHUIS
MOD
Plesmanlaan 121
AMSTERDAM
1066 CX
NETHERLANDS

- | | |
|---|-----------------|
| 1. Datum gegevens | 04-05-2005 |
| 2. Doorsnede tumor (volgens PA) | 12 |
| 3. Maligniteitsgraad | 2 = II |
| 4. MAI (2mm ²) | 5 |
| 5. ER-receptor | 1 = positief |
| 6. PR-receptor | 1 = positief |
| 7. HER-2/neu | 0 = negatief |
| 8. Lymfeklier status | 0 = N- negatief |
| 9. Is het formulier compleet en juist ingevuld? | Ja |

Patient has been assigned patient number [REDACTED]

ALEA igr - Release: 2.2 build: 2070 - Microsoft Internet Explorer

Bestand Bewerken Beeld Favorieten Extra Help Koppelingen »

Adres <https://fr.tenalea.net/igr/alea/Default.aspx> Ga naar

ALEA Randomisation program

From Study Result code

To User Operation Containing

| Timestamp | Study / form | User | Action | Result |
|------------------|--------------|---|--------|--|
| 06/12/2006 15:49 | CHIPOVAC | CN=iacobelli,OU=IGR,OU=fr,DC=onconnect,DC=net | INSERT | 0
AlgorithmLog ServiceLog DebugLog SQLLog ODM Request ODM Response Process this request again |
| 06/12/2006 15:32 | CHIRIODE | CN=iacobelli,OU=IGR,OU=fr,DC=onconnect,DC=net | INSERT | 0
AlgorithmLog ServiceLog DebugLog SQLLog ODM Request ODM Response Process this request again |
| 06/12/2006 15:31 | CHIRIODE | CN=iacobelli,OU=IGR,OU=fr,DC=onconnect,DC=net | INSERT | 0
AlgorithmLog ServiceLog DebugLog SQLLog ODM Request ODM Response Process this request again |
| 06/12/2006 15:30 | CHIRIODE | CN=iacobelli,OU=IGR,OU=fr,DC=onconnect,DC=net | INSERT | 0
AlgorithmLog ServiceLog DebugLog SQLLog ODM Request ODM Response Process this request again |
| 06/12/2006 15:28 | CHIRIODE | CN=iacobelli,OU=IGR,OU=fr,DC=onconnect,DC=net | INSERT | 0
AlgorithmLog ServiceLog DebugLog SQLLog ODM Request ODM Response Process this request again |
| 06/12/2006 10:48 | DEPISTORL | CN=pbr.depistorl,OU=IGR,OU=fr,DC=onconnect,DC=net | INSERT | 0
AlgorithmLog ServiceLog DebugLog SQLLog ODM Request ODM Response Process this request again |
| 06/12/2006 10:45 | VELCADE | CN=ducourt,OU=IGR,OU=fr,DC=onconnect,DC=net | INSERT | 0
AlgorithmLog ServiceLog DebugLog SQLLog ODM Request ODM Response Process this request again |
| 06/12/2006 10:03 | TESTGORTEC | CN=Wartelle,OU=IGR,OU=fr,DC=onconnect,DC=net | INSERT | 0
AlgorithmLog ServiceLog DebugLog SQLLog ODM Request ODM Response Process this request again |
| 06/12/2006 09:00 | MARGES-ORL | CN=ducourt,OU=IGR,OU=fr,DC=onconnect,DC=net | INSERT | 0
AlgorithmLog ServiceLog DebugLog SQLLog ODM Request ODM Response Process this request again |
| 05/12/2006 10:20 | MARGES-ORL | CN=ducourt,OU=IGR,OU=fr,DC=onconnect,DC=net | INSERT | 0
AlgorithmLog ServiceLog DebugLog SQLLog ODM Request ODM Response Process this request again |
| 04/12/2006 16:49 | ACCORD09 | CN=abbas,OU=IGR,OU=fr,DC=onconnect,DC=net | INSERT | 0
AlgorithmLog ServiceLog DebugLog SQLLog ODM Request ODM Response Process this request again |
| 04/12/2006 15:22 | TEST | CN=gros,OU=IGR,OU=fr,DC=onconnect,DC=net | INSERT | 0
AlgorithmLog ServiceLog DebugLog SQLLog ODM Request ODM Response Process this request again |
| 04/12/2006 11:02 | TEST | CN=gros,OU=IGR,OU=fr,DC=onconnect,DC=net | INSERT | 0
AlgorithmLog ServiceLog DebugLog SQLLog ODM Request ODM Response Process this request again |
| 04/12/2006 | | | | AlgorithmLog ServiceLog DebugLog SQLLog |

Navigation: Studies, Study definition, Address Book, System administration, Language Settings, System Settings, JSCRIPT Function Library, ALEA Users, Login Accounts, Templates, Edit role permissions, Images, View Permissions, Audit gateway log, Login log, Edit Greeting Message, **Audit log**, Online Help, Personal Settings

Internet

0:52:13:109 - Start processing ODM request at: Friday, December 01, 2006 / 12:52:13 AM
 0:52:13:109 - Processing clinical data section for study: [EMCColonScreening] Study_ID=183
 0:52:13:125 - Processing formdata section for subject: [] Study_ID=183
 0:52:13:453 - Allocating patient number: 120
 0:52:13:453 - Starting randomisation Test A, B, C or D at: Friday, December 01, 2006 / 12:52:13 AM
 0:52:13:468 - Stratification factors and patient allocation

| Current patient totals for the subjects' strata levels | | | | |
|--|------------|------------|------------|------------|
| Stratification factor and subject level | Test A (3) | Test B (3) | Test C (3) | Test D (1) |
| AGE=52 | 14 (11) | 11 (9) | 14 (11) | 5 (12) |
| REGIO=891 | 35 (29) | 37 (30) | 34 (28) | 13 (32) |
| MALE=1 | 16 (13) | 16 (13) | 16 (13) | 6 (15) |

0:52:13:500 -

| <i>Total amount of imbalance for the subjects' strata levels if treatment k were assigned to this subject</i> | | | | |
|---|--------------|--------------|--------------|--------------|
| Stratification factor and subject level | k=Test A (3) | k=Test B (3) | k=Test C (3) | k=Test D (1) |
| AGE | 3 | 2 | 3 | 4 |
| REGIO | 4 | 4 | 3 | 5 |
| MALE | 2 | 2 | 2 | 3 |

0:52:13:500 -

| <i>Lack of balance for the subjects' strata levels</i> | | | | |
|--|------------|------------|------------|------------|
| | Test A (3) | Test B (3) | Test C (3) | Test D (1) |
| Total imbalance when allocating treatment: | 9 | 8 | 8 | 12 |

0:52:13:515 - Performing randomisation with methodology: AMIN
 0:52:13:531 - Deriving minimum imbalance, trt_id=[1] treatmetRelevance=[select dbo.uf_emccolonscreening_1(atq(address),1, '@datatable')] trtImbalance=[9]
 0:52:13:671 - Deriving minimum imbalance, trt_id=[2] treatmetRelevance=[select dbo.uf_emccolonscreening_1(atq(address),2, '@datatable')] trtImbalance=[8]
 0:52:13:687 - Deriving minimum imbalance, trt_id=[3] treatmetRelevance=[select dbo.uf_emccolonscreening_1(atq(address),3, '@datatable')] trtImbalance=[8]
 0:52:13:718 - Deriving minimum imbalance, trt_id=[4] treatmetRelevance=[select dbo.uf_emccolonscreening_1(atq(address),4, '@datatable')] trtImbalance=[12]
 0:52:13:750 - Number of stratification factors=3, Lowest imbalance=8
 0:52:13:750 - Therefore with Adapted Minimisation performing treatment allocation based on minimisation.
 0:52:13:812 - Treatment Test B will be put into the urn 3 times
 0:52:13:937 - Treatment Test C will be put into the urn 3 times
 0:52:13:984 - Urn contains: 2,2,2,3,3,3
 0:52:13:984 - Randomly drew element 6 from the urn, treatment allocated=Test C(id=3)
 0:52:13:984 - Treatment allocated=3
 0:52:13:984 - Completed randomisation at: Friday, December 01, 2006 / 12:52:13 AM
 0:52:14:281 - Checking if study needs to be closed on fixed accrual.
 0:52:14:296 - Variables assigned.
 0:52:14:312 - SaveForm completed successfully

ALEA erasmusmc - Release: 2.2 build: 2075 - Microsoft Internet Explorer

Bestand Bewerken Beeld Favorieten Extra Help

Adres: <http://www.tenalea.com/erasmusmc/alea/Default.aspx> Koppelingen Ga naar

ALEA Randomisation program

- Studies
 - Open Studies
 - Pending Studies
 - Suspended Studies
 - EMCColonScreening
 - Data entry
 - Notification Queue
 - Resend Notifications
 - Reports
 - testreport
 - Accrual by Month
 - depterslist
 - Study definition listing
 - instituteaccrual
 - No title --
 - rutroetroutiu
 - Accrual by institute over n
 - Stratification Totals**
 - Patient listing
 - Accrual by Clinician
 - Delete Patient Record
 - Batch Subject Processing
 - Closed Studies
- Study definition
- Address Book
- Content Management
- Personal Settings
- System administration
 - Language Settings
 - System Settings
 - JSCRIPT Function Library
- ALEA Users
- Login Accounts
- Templates
- Edit role permissions
- Images
- View Permissions
- Audit gateway log
- Login log
- Edit Greeting Message
- Audit log
- Online Help

Study information: EMCColonScreening

EMCColonScreening -

| | | | |
|-----------------|-------------------------------|--------------------|---------|
| Status: | SUSP | Scope: | LOC |
| Access Type: | WHITE | Phase: | Phase 1 |
| Date activated: | 2006-05-29 | Date to close: | |
| Date completed: | | Date closed: | |
| Study accrual: | 0 | Patient numbering: | INCR |
| Forms: | RANDOMISATION - Patients: 152 | | |

Form: RANDOMISATION

Randomisation: Test A, B, C or D

Stratification factor: Age of the subject

| | No. of patients |
|--------|-------------------|
| 0-55 | |
| Test A | 14 |
| Test B | 14 |
| Test C | 11 |
| Test D | 4 |
| 55-60 | |
| Test A | 12 |
| Test B | 12 |
| Test C | 14 |
| Test D | 5 |
| 60-65 | |
| Test A | 8 |
| Test B | 9 |
| Test C | 10 |
| Test D | 4 |
| 65-70 | |
| Test A | 7 |
| Test B | 8 |
| Test C | 7 |
| Test D | 2 |
| 70-75 | |
| Test A | 4 |
| Test B | 3 |
| Test C | 3 |
| Test D | 1 |
| | Total: 152 |

Stratification factor: Gender of the patient is male

| | No. of patients |
|--------|-------------------|
| No | |
| Test A | 24 |
| Test B | 27 |
| Test C | 25 |
| Test D | 9 |
| Yes | |
| Test A | 21 |
| Test B | 19 |
| Test C | 20 |
| Test D | 7 |
| | Total: 152 |

Stratification factor: Regio

Gereed Internet

EA Randomisation program

études

Définition de l'étude

Créer une nouvelle étude

étude ouverte

étude en cours

AGSTEST1

EWING99

Statut de l'étude

Gestion de la numérotation

Librairie de code javascript

Formulaires

Créer un nouveau form

Enregistrement

Notifications

Questions

Tester la saisie

Générer des données

Effacer les données

Permissions du form

Exporter les données

Générer un script d

Randomisation

Randomisations

Personnes concernées

Instuts concernés

Exporte les données (tous

Importer des données

Effacer les données de test

MacroOptions

Rapports

Study user permissions

GEMOX-A

ISSUE283

LISTERANDO

Lung ART

NSGCT poor

OS 2006

PROST

utilisateur: System Administrator



Software for randomisation in clinical trials

EWING99 - Enregistrement

Use the ':' character to separate multiple values within a studyquestion.
Questions marked with "*" are stratification factors.

| | |
|---|---|
| Investigateur | <input type="checkbox"/> Laplanche, - Institut GUSTAVE-ROUSSY
<input type="checkbox"/> Le Deley, - Institut GUSTAVE-ROUSSY |
| Number of patients | <input type="text" value="500"/> |
| GROUP | <input type="text" value="1:2:3"/> |
| Patient's surname (long) | <input type="text" value="x"/> |
| Patient's Firstname | <input type="text" value="x"/> |
| Date of birth | <input type="text" value="1/1/1950-1/1/1970"/> |
| Hospital Number | <input type="text" value="x"/> |
| Sex | <input type="text" value="1:1:1:2"/> |
| Date of biopsy or initial surgery | <input type="text"/> |
| Ewing tumour or PNET diagnosed by the local pathologist | <input type="text"/> |
| Previous treatment (other than primary surgery) | <input type="text"/> |
| Ewing tumour as second malignancy | <input type="text"/> |
| Medical contraindication for planned chemotherapy | <input type="text"/> |
| Day 1 of first course of VIDE chemotherapy (planned or completed) | <input type="text"/> |
| Signed informed consent | <input type="text"/> |
| Patient OK for the EURO-EWING 99 study | <input type="text"/> |
| Other metastatic | <input type="text"/> |
| <input type="button" value="Envoyer"/> | |

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T E N A L E A

TRANS EUROPEAN NETWORK FOR CLINICAL TRIALS SERVICES

Validation support

- Random generation of eligible subjects
- Supports test form entry
- Supports batch testdata submission
- Supports generation test patient populations
- Audit trail + algorithm log
- Strata totals reporting
- Generates validation script



T E N A L E A
TRANS EUROPEAN NETWORK FOR CLINICAL TRIALS SERVICES

Service availability

- 15 Academic clinical trial data centers now
- 75 clinical trial data centers by 2010
- SLA based service provision 2007
- For further info: tenalea@nki.nl