

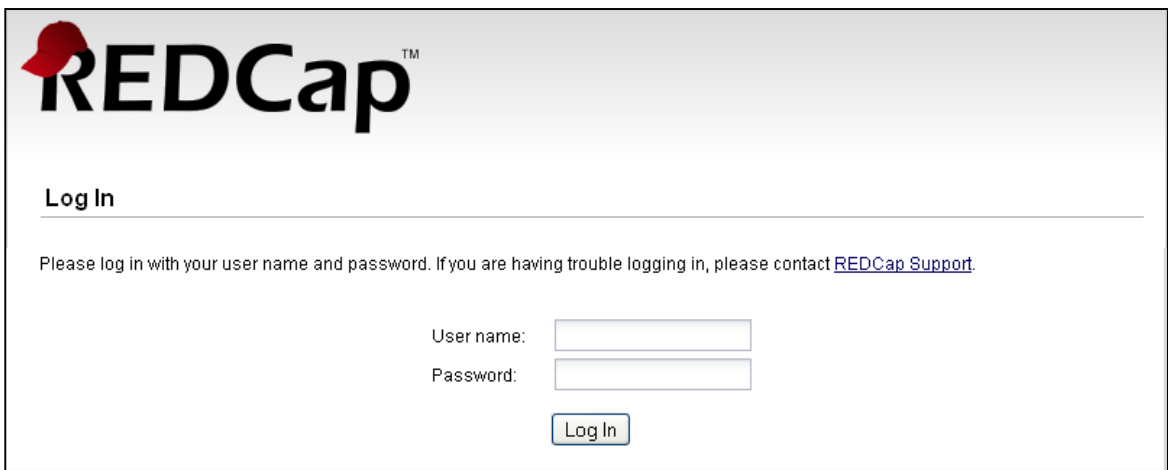
Patient Randomization protocollo ITP0207

Per accedere al database ITP0207 su REDCap e randomizzare un paziente

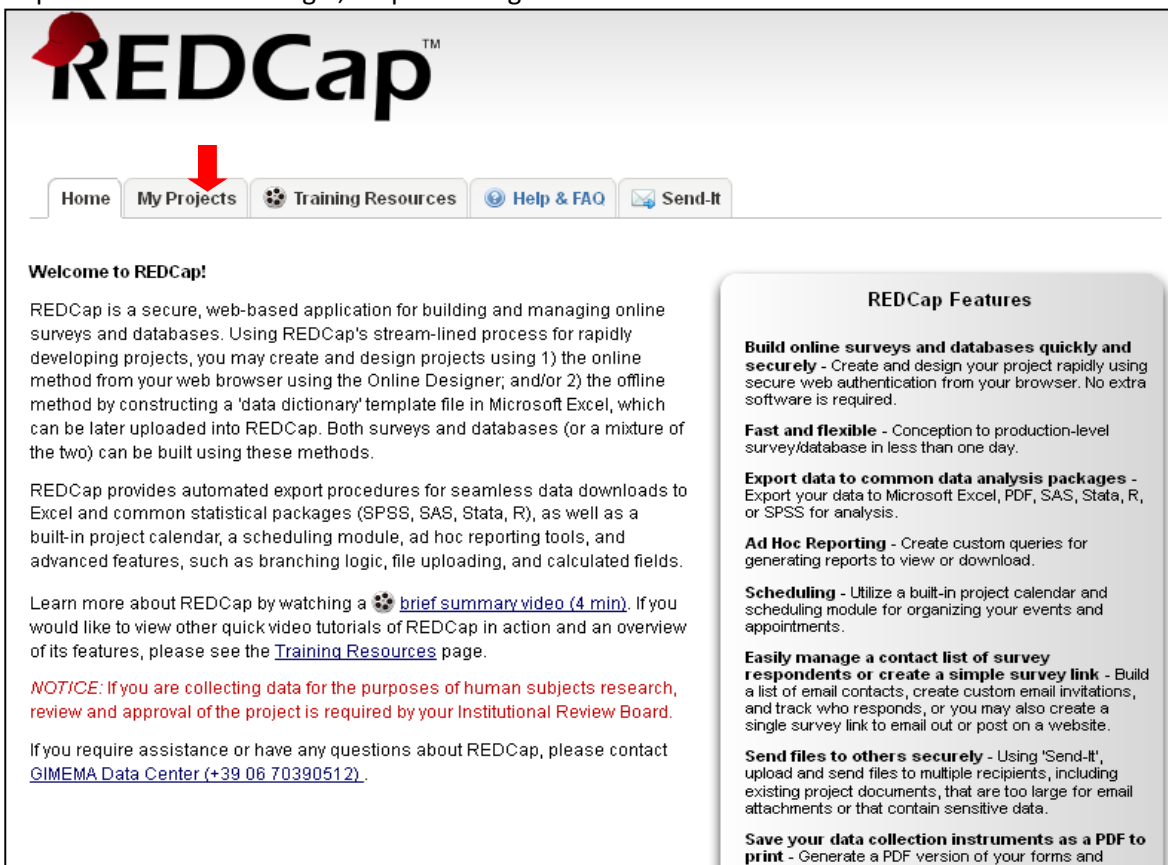
Per randomizzare un paziente nello studio ITP 0207 si può accedere al sistema REDCap in due modi:

1. Aprire un browser e digitare il seguente indirizzo: <https://redcap.gimema.it/redcap>
2. Dal sito GIMEMA www.gimema.it, cliccare su “Portale della Ricerca” e poi sul link di randomizzazione per lo studio ITP 0207.

A questo punto si aprirà la seguente schermata nella quale bisogna inserire la propria username e password (forniti per e-mail al momento dell’attivazione dell’utente):



Dopo aver effettuato il login, si aprirà la seguente schermata:



Welcome to REDCap!

REDCap is a secure, web-based application for building and managing online surveys and databases. Using REDCap's stream-lined process for rapidly developing projects, you may create and design projects using 1) the online method from your web browser using the Online Designer; and/or 2) the offline method by constructing a 'data dictionary' template file in Microsoft Excel, which can be later uploaded into REDCap. Both surveys and databases (or a mixture of the two) can be built using these methods.

REDCap provides automated export procedures for seamless data downloads to Excel and common statistical packages (SPSS, SAS, Stata, R), as well as a built-in project calendar, a scheduling module, ad hoc reporting tools, and advanced features, such as branching logic, file uploading, and calculated fields.

Learn more about REDCap by watching a [brief summary video \(4 min\)](#). If you would like to view other quick video tutorials of REDCap in action and an overview of its features, please see the [Training Resources](#) page.

NOTICE: If you are collecting data for the purposes of human subjects research, review and approval of the project is required by your Institutional Review Board.

If you require assistance or have any questions about REDCap, please contact [GIMEMA Data Center \(+39 06 70390512\)](#).

REDCap Features

- Build online surveys and databases quickly and securely** - Create and design your project rapidly using secure web authentication from your browser. No extra software is required.
- Fast and flexible** - Conception to production-level survey/database in less than one day.
- Export data to common data analysis packages** - Export your data to Microsoft Excel, PDF, SAS, Stata, R, or SPSS for analysis.
- Ad Hoc Reporting** - Create custom queries for generating reports to view or download.
- Scheduling** - Utilize a built-in project calendar and scheduling module for organizing your events and appointments.
- Easily manage a contact list of survey respondents or create a simple survey link** - Build a list of email contacts, create custom email invitations, and track who responds, or you may also create a single survey link to email out or post on a website.
- Send files to others securely** - Using 'Send-It', upload and send files to multiple recipients, including existing project documents, that are too large for email attachments or that contain sensitive data.
- Save your data collection instruments as a PDF to print** - Generate a PDF version of your forms and surveys for existing or offline data collection.

Cliccare su “My Project” e selezionare il progetto “ITP 0207” o “ITP 0207 emendato” tra i progetti ai quali si ha accesso:

REDCap™

Home My Projects Training Resources Help & FAQ Send-It

Listed below are the REDCap projects to which you currently have access. Click the project title to open the project. Newly created projects begin in **Development status** as you begin to build and design them. When you are ready to begin entering real data in the project, you may move it to **Production status** to designate the project as officially collecting data. When you are finished collecting data or if you wish to stop collection, the project may be set to **Inactive status**, although it may be brought back to Production status at any time when you are ready to begin collecting data again. Also listed is the project type, which designates if the project is in **classic** or **longitudinal** data collection format.

Project Title	Records	Fields	Instruments	Type	Status
MDS0413	36	196	5 forms		✓
ITP0207	6	28	1 form		✓
ITP0207 emendato	0	29	1 form		✓
EMATO0213	16	387	19 forms		

Una volta aperto il progetto, avrà la seguente schermata con due opzioni per inserire i dati del nuovo paziente da randomizzare:

- ✓ Cliccando su “Add/Edit Records”
- ✓ Cliccando su “Randomization Checklist”

REDCap™

GIMEMA Foundation

ITP0207 emendato

Logged in as enrico_crea | Log out

My Projects

Project Home Project Setup

Project status: **Production**

Data Collection

Record Status Dashboard

Add / Edit Records

Randomization Checklist

Applications

Field Comment Log

File Repository

Report Builder

Project Bookmarks

autonotify

Help & Information

Help & FAQ

Video Tutorials

Suggest a New Feature

If you are experiencing problems, please contact your REDCap administrator.

Project Home Project Setup

Quick Tasks

Codebook

Create a report

The Codebook is a human-readable, read-only version of the project's Data Dictionary and serves as a quick reference for viewing field attributes.

Build custom reports for quick views of your data, and export reports to Excel/CSV.

Project Dashboard

The tables below provide general dashboard information, such as a list of all users with access to this project, general project statistics, and upcoming calendar events (if any).

Current Users	
User	Expires
alfonso_piococchi (alfonso_piococchi)	never
enrico_crea (enrico_crea)	never
francesca_paoloni (francesca_paoloni)	never
laura_didonato	never

Project Statistics	
Records in project	Total: 0 / In group: 0
Most recent activity	08/26/2014 9:47am
Space usage for docs	0.00 MB
Project status	✓ Production

Cliccando una delle due opzioni sopra elencate si aprirà la seguente tabella nella schermata principale:

The screenshot displays the REDCap interface for the GIMEMA Foundation project. The left sidebar contains navigation options: My Projects, Project Home, Project Setup (Production), Data Collection (Record Status Dashboard, Add/Edit Records), Applications (Field Comment Log, File Repository, Report Builder), Project Bookmarks (autontify), and Help & Information. The main content area is titled "GIMEMA Foundation" and "ITP0207 emendato". It features a "Download PDF of instrument(s)" button and a "Randomization Checklist" section. Below this, there are instructions and a table showing record counts: Total records: 0 / In group: 0, Incomplete Records (0), and Complete Records (0). Each record count has a corresponding dropdown menu. An "Add new record" button is present. A "Data Search" section includes a "Choose a field to search" dropdown and a "Search query" input field.

Da qui si potranno oltre a visualizzare i pazienti già randomizzati, anche inserire nuovi casi nel database da randomizzare.

Nota: Cliccando su “Record Status Dashboard” nel menu di sinistra, nella schermata principale, si aprirà la tabella dove potrà visualizzare i dati dei pazienti già inseriti.

Per randomizzare un nuovo paziente deve cliccare su “Add new record” e si aprirà la CRF nella quale inserire i dati del paziente e procedere alla randomizzazione:

REDCap™

Logged in as **enrico_crea** | Log out

My Projects
 Project Home
 Project Setup
 Project status: **Production**

Data Collection

Record Status Dashboard
 Add / Edit Records

Random Code **207155-1** [Select other record](#)

Data Collection Instruments:
Randomization Checklist

Applications

Field Comment Log
 File Repository
 Report Builder

Project Bookmarks

autonotify

Help & Information

Help & FAQ
 Video Tutorials
 Suggest a New Feature

If you are experiencing problems, please contact your [REDCap administrator](#).

GIMEMA Foundation
ITP0207 emendato

Actions: [Download PDF of instrument\(s\)](#)

[VIDEO: Basic data entry](#)

Randomization Checklist

Adding new Random Code 207155-1

Random Code 207155-1

Initials * must provide value

Sex male female * must provide value [reset](#)

Date of birth * must provide value Today D-M-Y

Date of signed informed consent * must provide value Today D-M-Y

Date of diagnosis * must provide value Today D-M-Y

Inclusion Criteria

Signed written informed consent according to IGH/EU/GCP and national local laws Yes No * must provide value [reset](#)

Newly diagnosed untreated ITP adult patients Yes No * must provide value [reset](#)

Age ≥ 18 and ≤ 80 years Yes No * must provide value [reset](#)

Platelet count $\leq 20 \times 10^9/L$ or Platelet count $> 20 \times 10^9/L$ and $< 50 \times 10^9/L$ plus bleeding with score ≥ 8 (according to [grading scale, paragraph 7.4](#)) Yes No

La CRF sopra riportata è un form di randomizzazione nella quale viene verificata l'eleggibilità del paziente. Il form è suddiviso in 4 sezioni:

1. Sezione di dati anagrafici nella quale viene generato automaticamente il "Random Code" (tutti i campi sono obbligatori)

Randomization Checklist

Adding new Random Code 207155-1

Random Code 207155-1

Initials * must provide value











Sex male female * must provide value [reset](#)

Date of birth * must provide value Today D-M-Y





















Date of signed informed consent * must provide value Today D-M-Y

Date of diagnosis * must provide value Today D-M-Y

2. La sezione dei criteri di inclusione (tutti i campi sono obbligatori):

Inclusion Criteria			
Signed written informed consent according to IGH/EU/GCP and national local laws <small>* must provide value</small>	<input type="radio"/> Yes <input type="radio"/> No	 	reset
Newly diagnosed untreated ITP adult patients <small>* must provide value</small>	<input type="radio"/> Yes <input type="radio"/> No	 	reset
Age ≥ 18 and ≤ 80 years <small>* must provide value</small>	<input type="radio"/> Yes <input type="radio"/> No	 	reset
Platelet count $\leq 20 \times 10^9/L$ or Platelet count $> 20 \times 10^9/L$ and $< 50 \times 10^9/L$ plus bleeding with score ≥ 8 (according to grading scale at paragraph 7.1) <small>* must provide value</small>	<input type="radio"/> Yes <input type="radio"/> No	 	reset
Baseline Quality of Life evaluation questionnaire filled in <small>* must provide value</small>	<input type="radio"/> Yes <input type="radio"/> No	 	reset

3. La sezione dei criteri di esclusione (tutti i campi sono obbligatori):

Exclusion Criteria			
Active malignancy at time of study entry <small>* must provide value</small>	<input type="radio"/> Yes <input type="radio"/> No	 	reset
Steroids administration (PDN ≤ 1 mg/Kg/day) for more than 5 days before randomization <small>* must provide value</small>	<input type="radio"/> Yes <input type="radio"/> No	 	reset
Concomitant treatment with anti-platelet and or anti-coagulant drugs <small>* must provide value</small>	<input type="radio"/> Yes <input type="radio"/> No	 	reset
Concomitant severe psychiatric disorders <small>* must provide value</small>	<input type="radio"/> Yes <input type="radio"/> No	 	reset
Not confirmed diagnosis of ITP for: 1) Positivity of autoimmunity markers: antinucleus ($\geq 1:80$), anti-tireoglobulin, anti-tireoperoxidase, anti-cardiolipin (≥ 40 GPL U/mL), anti-2glycoprotein (≥ 40 IgG U/mL) antibodies, Lupus Anticoagulant (KCT ratio, RVVT ratios ≥ 1.5 times the upper normal limit), direct antiglobulin test (DAT) 2) Presence of autoimmune hemolytic anemia 3) Presence of connective tissue disease <small>* must provide value</small>	<input type="radio"/> Yes <input type="radio"/> No	 	reset
Women who are pregnant or breastfeeding <small>* must provide value</small>	<input type="radio"/> Yes <input type="radio"/> No	 	reset
Cardiovascular diseases and diabetes requiring treatment <small>* must provide value</small>	<input type="radio"/> Yes <input type="radio"/> No	 	reset
Severe non-controlled, despite therapy, hypertension and diabetes <small>* must provide value</small>	<input type="radio"/> Yes <input type="radio"/> No	 	reset
Liver and kidney function impairment (creatinine, ALT, AST > 2 times upper normal limit) <small>* must provide value</small>	<input type="radio"/> Yes <input type="radio"/> No	 	reset
UCVAb, HIVAb, HBeAg, HBeAb seropositive status	<input type="radio"/> Yes <input type="radio"/> No	 	reset

Nota: Sotto i criteri di esclusione, nel campo “Comments”, è possibile inserire, ove ritenuto necessario, commenti supplementari.

In caso di non eleggibilità, misurata sui valori assunti nei criteri sopra indicati, comparirà un messaggio di warning:

Sorry, the patient is ineligible!

In caso di eleggibilità, comparirà il seguente messaggio:

The patient is eligible. Please, randomize him!

A questo punto è possibile passare alla sezione 4:

4. Randomization

Per randomizzare il paziente bisogna cliccare sul tasto “Randomize”:

Randomization

Random ⓘ 🔗 Randomize

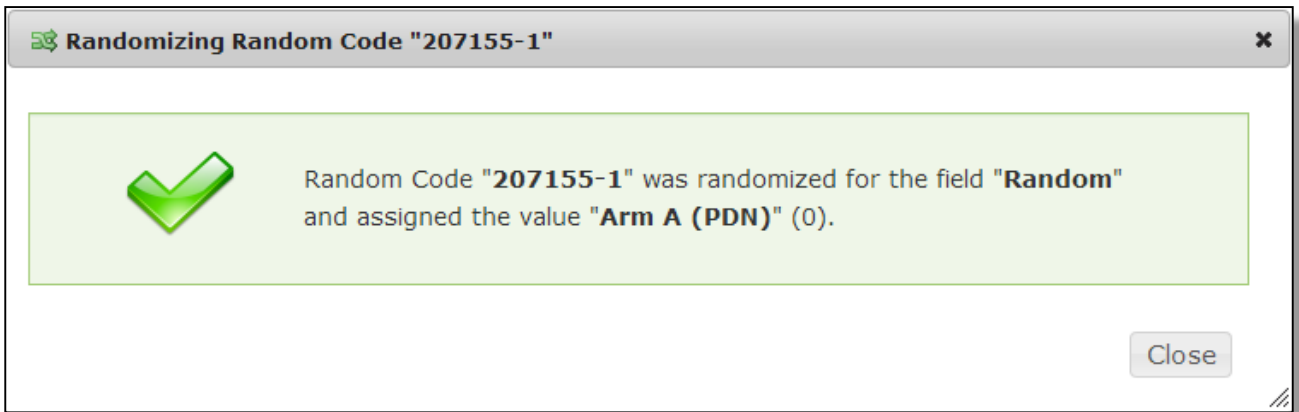
Comparirà la seguente schermata:

🔗 **Randomizing Random Code "207155-1"** ✕

Below you may perform randomization for Random Code "207155-1" on the field **Random** (*arm*).

Randomize Cancel

Cliccare **una volta** su “Randomize” ed **attendere** l’informazione sull’avvenuta randomizzazione tramite la seguente schermata:



Ora che il paziente è stato randomizzato (evidenziato sotto)

bisogna:

- Cambiare il campo “Complete?”

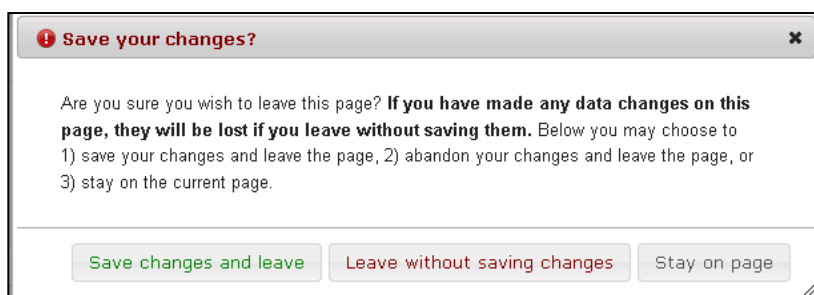
da “Incomplete”

a “Complete”

- **Salvare** la CRF cliccando su una delle opzioni di salvataggio in fondo alla pagina, non *c'è nessun salvataggio automatico in REDCap*. Le opzioni di salvataggio sono:

- ✓ “Save record” salva ed esce dal paziente
- ✓ “Save and Continue” salva e rimane nello stesso form per lo stesso paziente

Qualora si dimenticasse di salvare i dati inseriti e si volesse passare ad un'altra pagina, comparirà il seguente messaggio:



Dopo aver randomizzato il paziente

Al momento della randomizzazione viene inviata in automatico una mail dal sistema REDCap al GIMEMA Data Center che provvederà ad inserire in Lotus Notes (software dedicato alla raccolta dei dati dello studio) il paziente da lei randomizzato assegnando il SIC in modo che potrà procedere alla compilazione delle schede di raccolta dati successive.

Riceverà una mail di conferma da parte del GIMEMA Data Center dell'avvenuta registrazione in Lotus.

Riferimenti

Per qualsiasi problema è possibile contattare:

- la Data Manager Dr.ssa Mariangela Iodice (06/70390523, m.iodice@gimema.it)
- l'assistenza GIMEMA al sistema REDCap (assistenza.redcap@gimema.it)