#### Istituti Clinici Scientifici Maugeri

# La piattaforma REDCap negli studi clinici



DATABASE NEURO-ONCOLOGICO





# REDCap Research Electronic Data Capture





**Piattaforma web** che consente ai Ricercatori di collezionare e archiviare informazioni e risultati in un <u>ambiente sicuro</u>.

- Aderente ai principali riferimenti normativi in materia di trattamento dati personali (ICH GCP E-6 EU, 21 CFR Part 11 USA, GDPR 2016/679 EU)
- Piattaforma ad accesso controllato
- Installazione centro-specifica
- Accessibile mediante link pubblico (redcap.icsmaugeri.it)
- Supporto informatico per studi di ricerca no-profit
- Dati archiviati in forma pseudonima



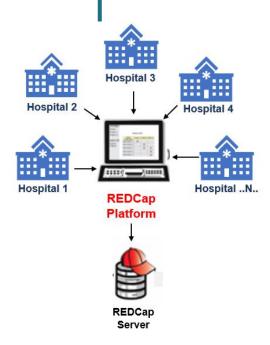


## FUNZIONALITA' PRINCIPALI DI REDCAP



#### La piattaforma REDCap consente di:

- Costruire schede raccolta dati elettroniche (eCRFs) personalizzate
- Archiviare grandi moli di dati
- > Strutturare i dati da raccogliere, definendone formato e tipologia
- Gestire studi mono e multicentrici e longitudinali
- Realizzare procedure di randomizzazione
- > Effettuare monitoraggio e controlli di qualità dei dati, sia real-time sia al termine del data entry
- Raccogliere attivamente dati da pazienti tramite la somministrazione di questionari online in ospedale con tablet oppure direttamente sullo smartphone del paziente a casa





# FASI DI GESTIONE DI UNO STUDIO CLINICO CON IL SUPPORTO REDCAP







## **ACCESSO ALLA PIATTAFORMA**



#### LOGIN MEDIANTE CREDENZIALI PERSONALI

REDCap®	
Log In	
Please log in with your user name and password	I. If you are having trouble logging in, please contact <u>Valentina Tibollo</u> .
	Username:
	Password:
	Log In Forgot your password?

#### Welcome to REDCap!

REDCap is a secure web platform for building and managing online databases and surveys. REDCap's streamlined process for rapidly creating and designing projects offers a vast array of tools that can be tailored to virtually any data collection strategy.

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 **B** <u>brief summary video (4 min)</u>, if you would like to view other quick video tutorials of REDCap in action and an overview of its features, please see the <u>Training Resources</u> 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  $\underline{\text{Valentina Tibollo}}.$ 

#### **REDCap Features**

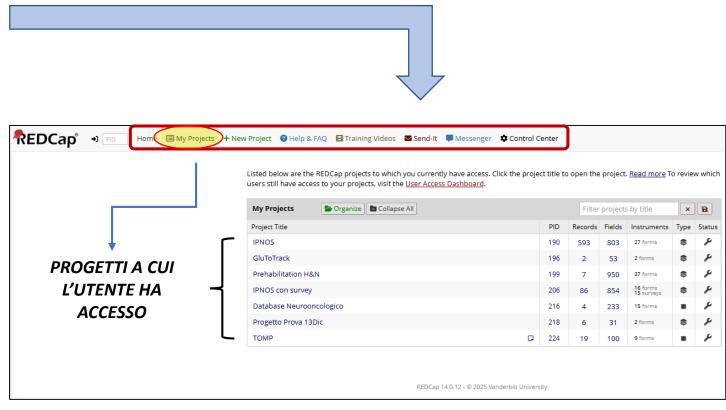
Build online surveys and databases quickly and securely in your browser - Create and design your project using a secure login from any device. No extra software required. Access from anywhere, at any time.

Fast and flexible - Go from project creation to starting data collection in less than one day. Customizations and changes are possible any time, even after data collection has begun.

Advanced instrument design features - Auto-validation, calculated fields, file uploading, branching/skip logic, and survey stop actions

**Diverse and flexible survey distribution options** - Use a list of email addresses or phone numbers for your survey respondents and automatically contact them with personalized messages, and track who has responded. Or create a simple link for an anonymous survey for mass email mailings, to post on a website, or print on a flyer.

Data quality - Use field validation, branching/skip logic, and Missing Data Codes to improve and protect data quality during data entry. Open data queries to automatically identify and resolve discrepancies and other issues real-time.

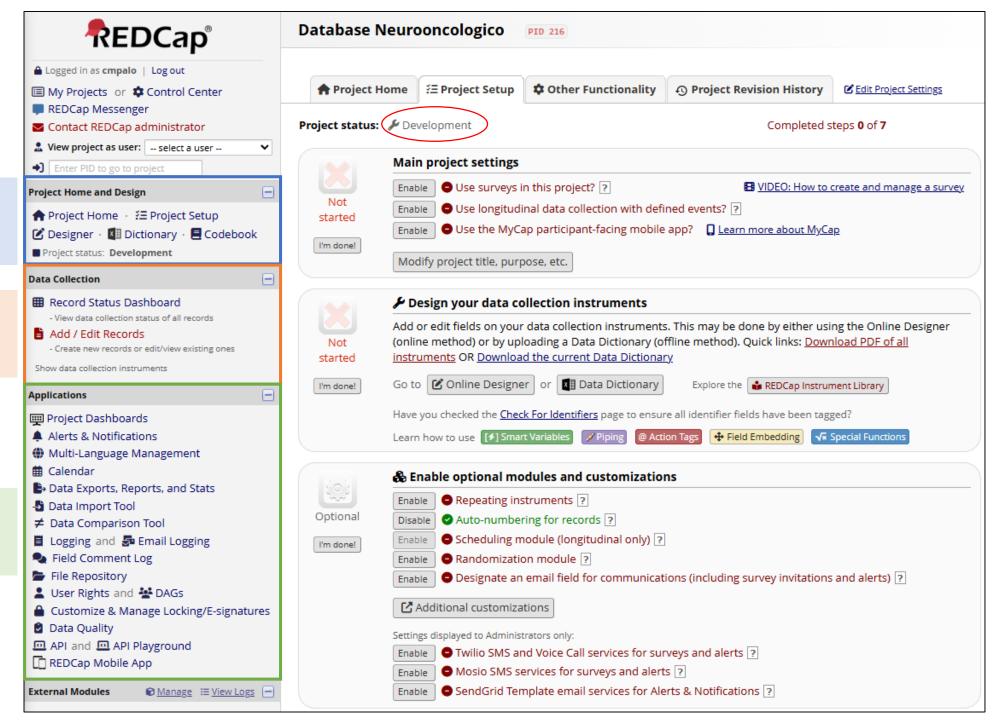




Definizione schede raccolta dati e costruzione campi

Inserimento e monitoraggio dei dati dei pazienti

Applicazioni / funzionalità della piattaforma



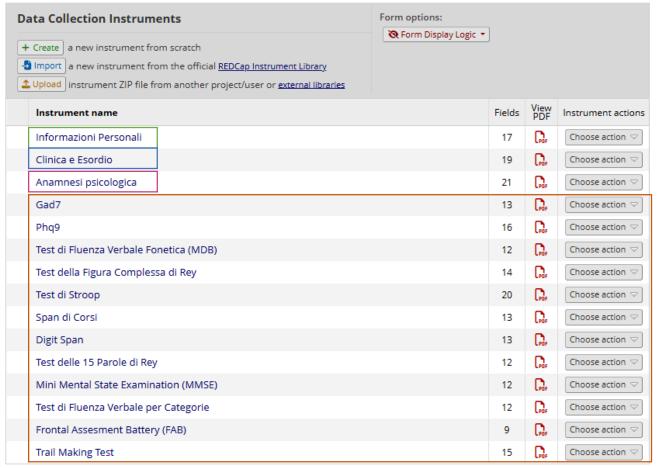


## **COSTRUZIONE DELLE eCRFs (1)**



n Project Home	₹Ξ Project Setup	② Online Designer	🗷 Data Dictionary	<b>■</b> Codebook
B VIDEO: How to use th	nis page	Create snapshot of ins	truments Last snapshot:	25/02/2025 12:37 ?

The Online Designer will allow you to make project modifications to fields and data collection instruments very easily using only your web browser. NOTE: While in development status, all field changes will take effect immediately in real time.



#### SCHEDE RACCOLTA DATI AD OGGI DISPONIBILI



Anagrafica del pazienti e informazioni su arruolamento in studio e consenso Quadro clinico: sintomatologia ed informazioni su risonanza magnetica Anamnesi psicologica: sintomatologia

**Test psicologici** con calcolo automatico di punteggi, corretti sulla base di età, scolarità e sesso del paziente



## **COSTRUZIONE DELLE eCRFs (2)**

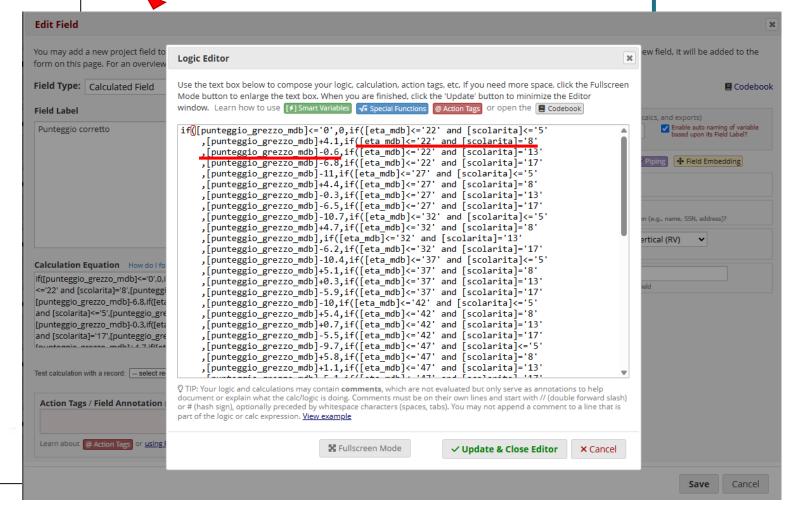


#### CORREZIONE PER ETA' E SCOLARITA'

Scolarità Età	5	8	13	17
20	4.1	-0.6	-6.8	-11
25	4.4	-0.3	-6.5	-10.7
30	4.7	0	-6.2	-10.4
35	5.1	0.3	-5.9	-10
40	5.4	0.7	-5.5	-9.7
45	5.8	1.1	-5.1	-9.3
50	6.3	1.5	-4.7	-8.8
55	6.8	2	-4.2	-8.4
60	7.3	2.5	-3.7	-7.8
65	7.9	3.2	-3.1	-7.2
70	8.6	3.9	-2.4	-6.5
75	9.4	4.7	-1.5	-5.7
80	10.4	5.7	-0.5	-4.7

P.C.	P.E. 0	
Da 0 a 17.34		
Da 17.35 a 21.32	1	
Da 21.33 a 25.15	2	
Da 25.16 a 30.40	3	
> 30.40	4	

#### Conversione delle tabelle di correzione dei punteggi dei test in regole informatiche

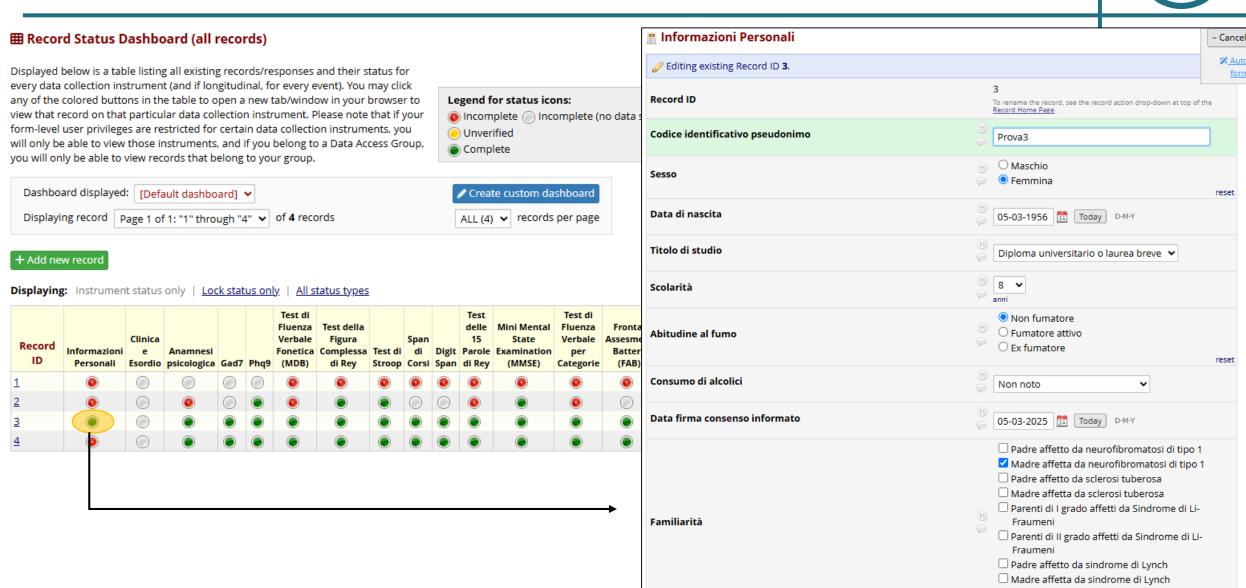




### RECORD STATUS DASHBOARD



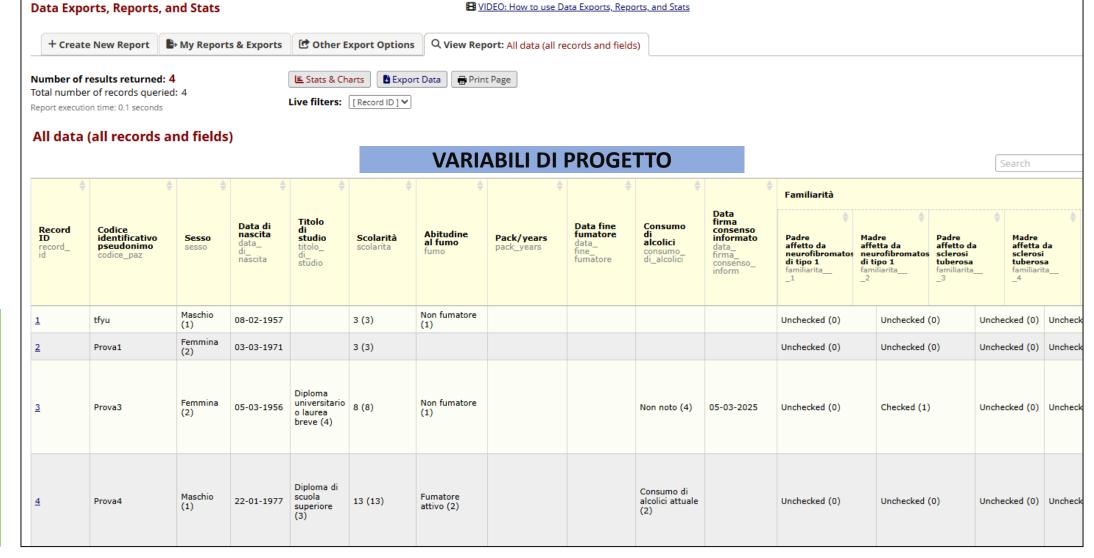
☐ Altro





### **DATABASE POPOLATO**









# Grazie per l'attenzione!