Royal Jubilee Hospital, Island Health
REDx 2019

USING REDCap TO ENHANCE ELECTRONIC DATA CAPTURE AND RESEARCH DATA MANAGEMENT IN CARDIAC PACING STUDIES

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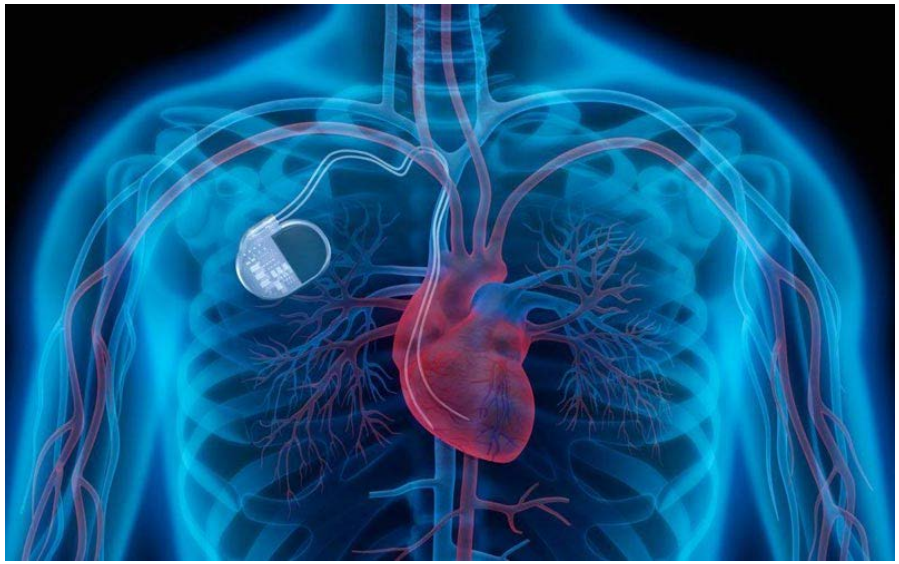
University of Sao Paulo Medical School

Heart Institute - Sao Paulo Medical School

Cardiac Implantable Electronic Devices



Complications

New techniques

REDCap

Pediatric Pacing

Quality of Life

IMPLEMENTING A DATA MANAGEMENT INFRASTRUCTURE

CHALLENGING SCENARIO

Lack of support for research activities & data management

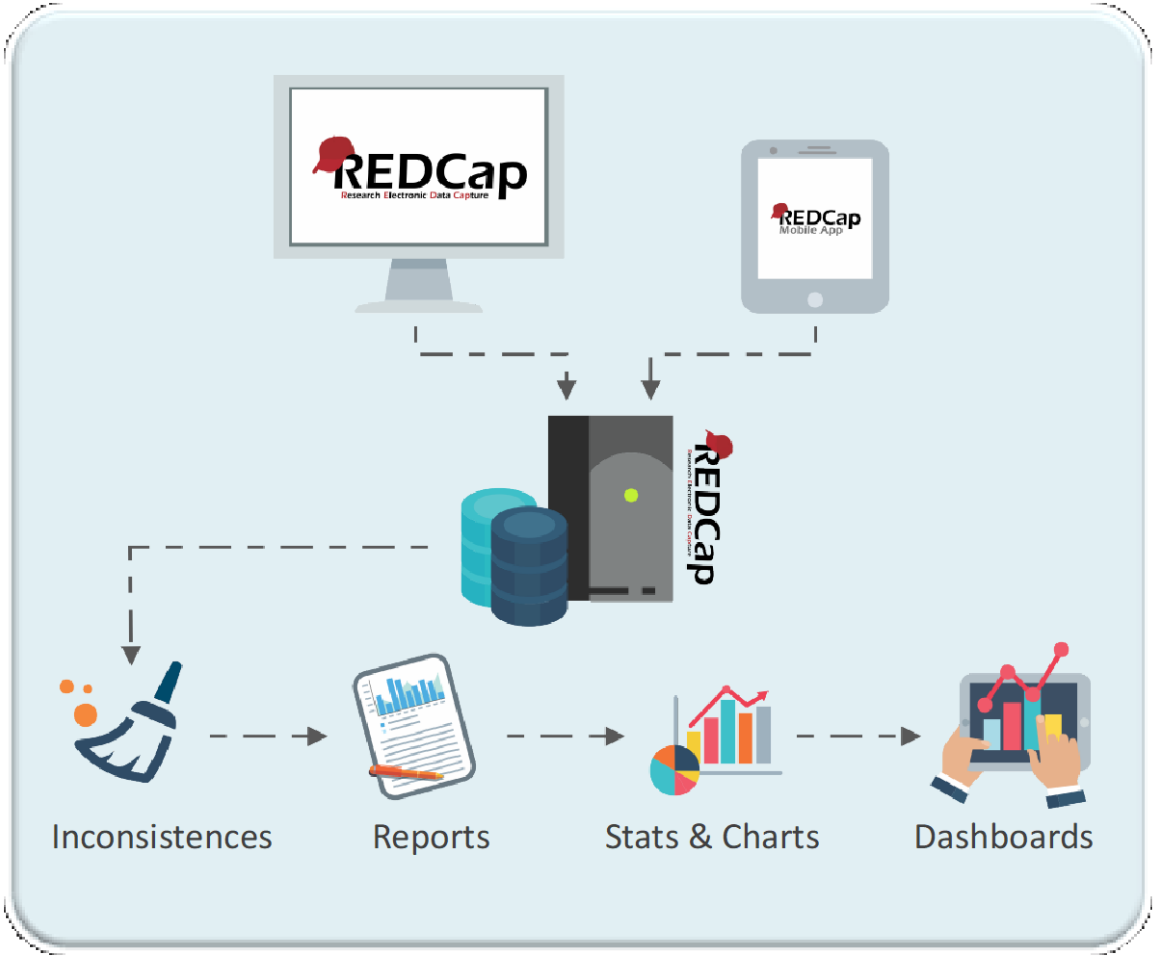
Lack of tools for electronic data collection

Lack of Data Protection, Storage and Security Policies

Lack of IT infrastructure & support

IMPLEMENTING A DATA MANAGEMENT INFRASTRUCTURE

DISRUPTIVE SOLUTION



IMPLEMENTING A DATA MANAGEMENT INFRASTRUCTURE

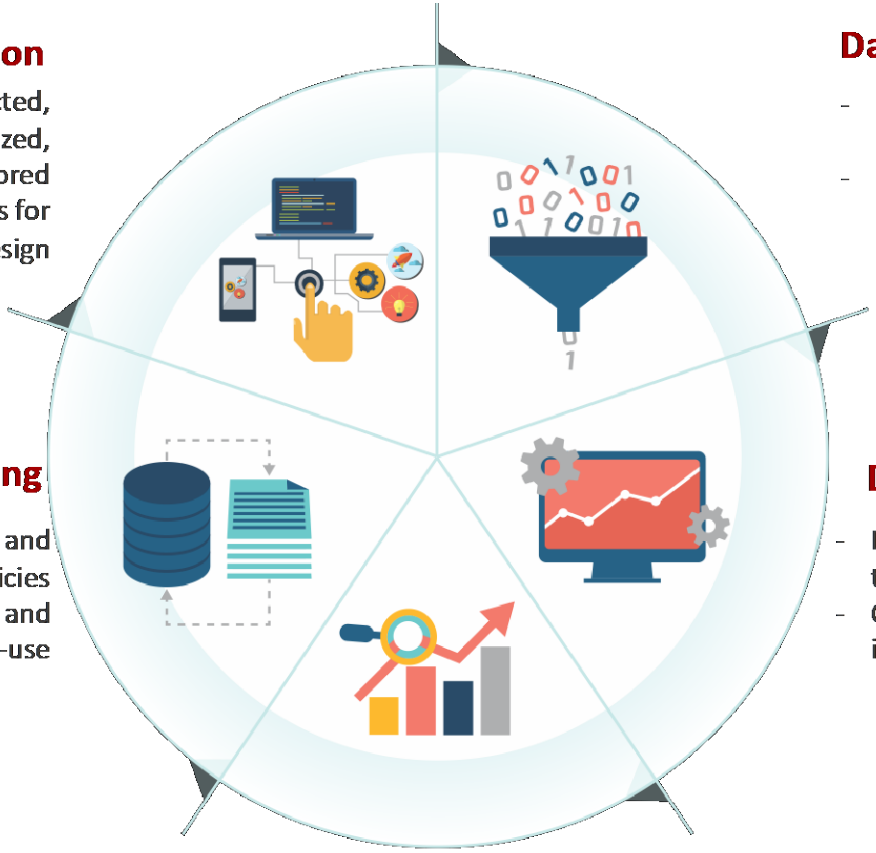
STEP 1 – DATA MANAGEMENT PLAN

Data Creation

- Identify which data will be collected, how it will be organized, documented and stored
- Consider specialized taxonomies for database design

Data Collection

- Collect data from experiments and surveys
- Online and off-line methods



Data Sharing

- Knowledge transfer, publishing and sharing policies
- Ensure data is discoverable and accessible for re-use

Data Management

- Data quality monitoring in real time
- Outliers, missing values and inconsistencies

Data Analysis

- Data visualization and analysis
- Verification, insights, discovery

IMPLEMENTING A DATA MANAGEMENT INFRASTRUCTURE

STEP 2 – DATABASE DESIGN

Eligibility

- Inclusion criteria
- Exclusion criteria

Baseline

- Demography
- Medical history
- Comorbidities

Intervention / Observation

- Treatments
- Exams
- Evaluations

Follow-up

- Follow-up visits
- Complications
- Adverse events
- PROMs

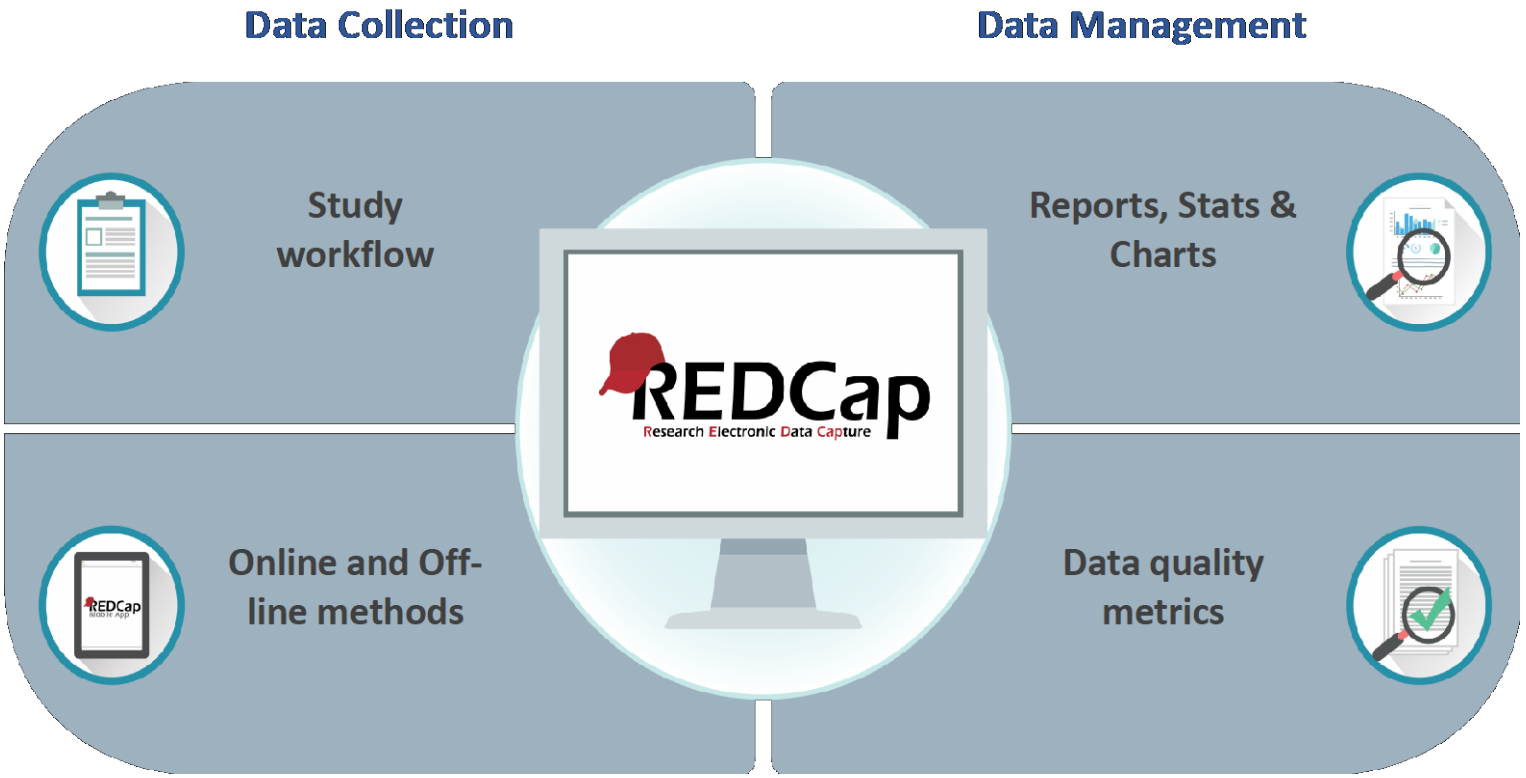
Outcomes

- End-points
- Losses and exclusions
- Deaths
- Study closing

Standardized CRF allowing the reuse across different studies

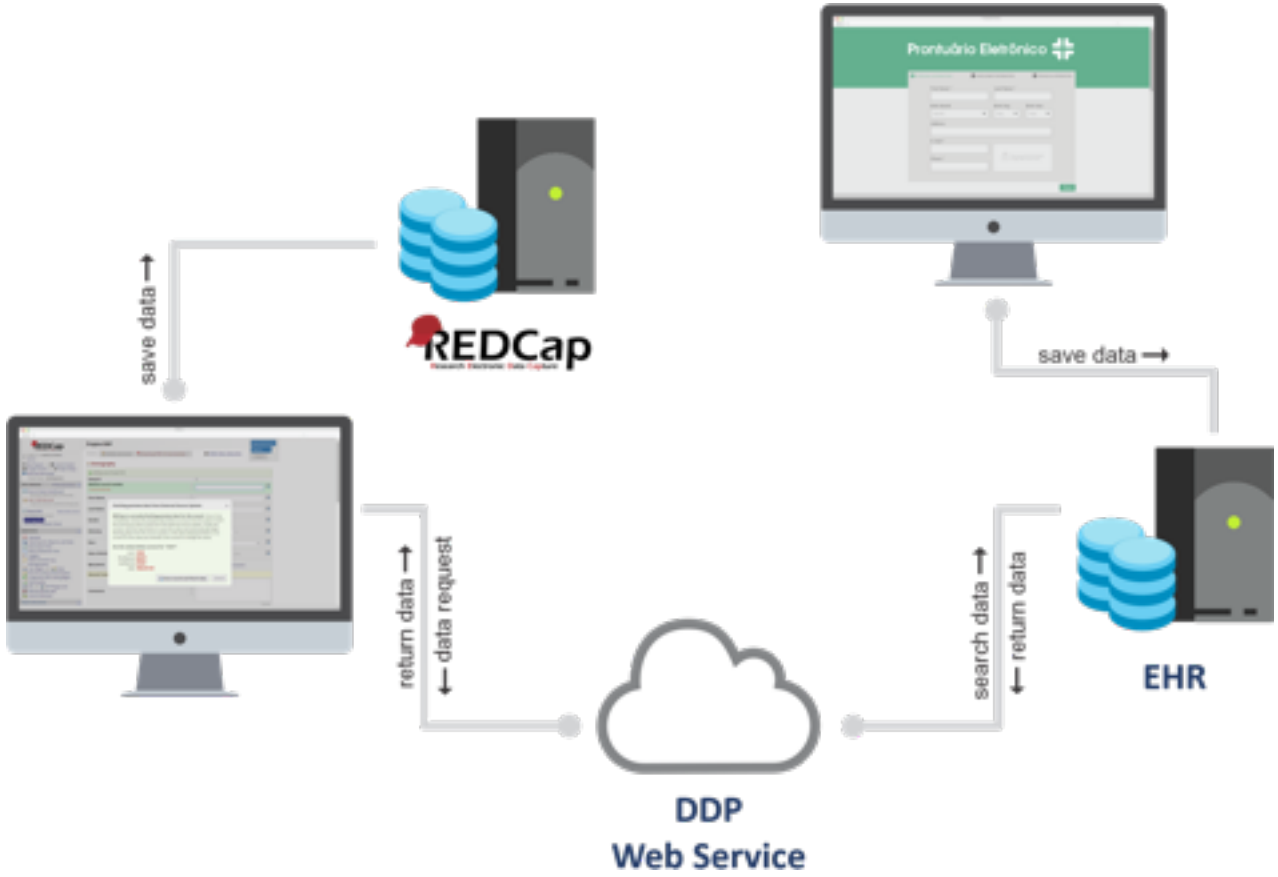
IMPLEMENTING A DATA MANAGEMENT INFRASTRUCTURE

STEP 3 – PERSONEL TRAINING



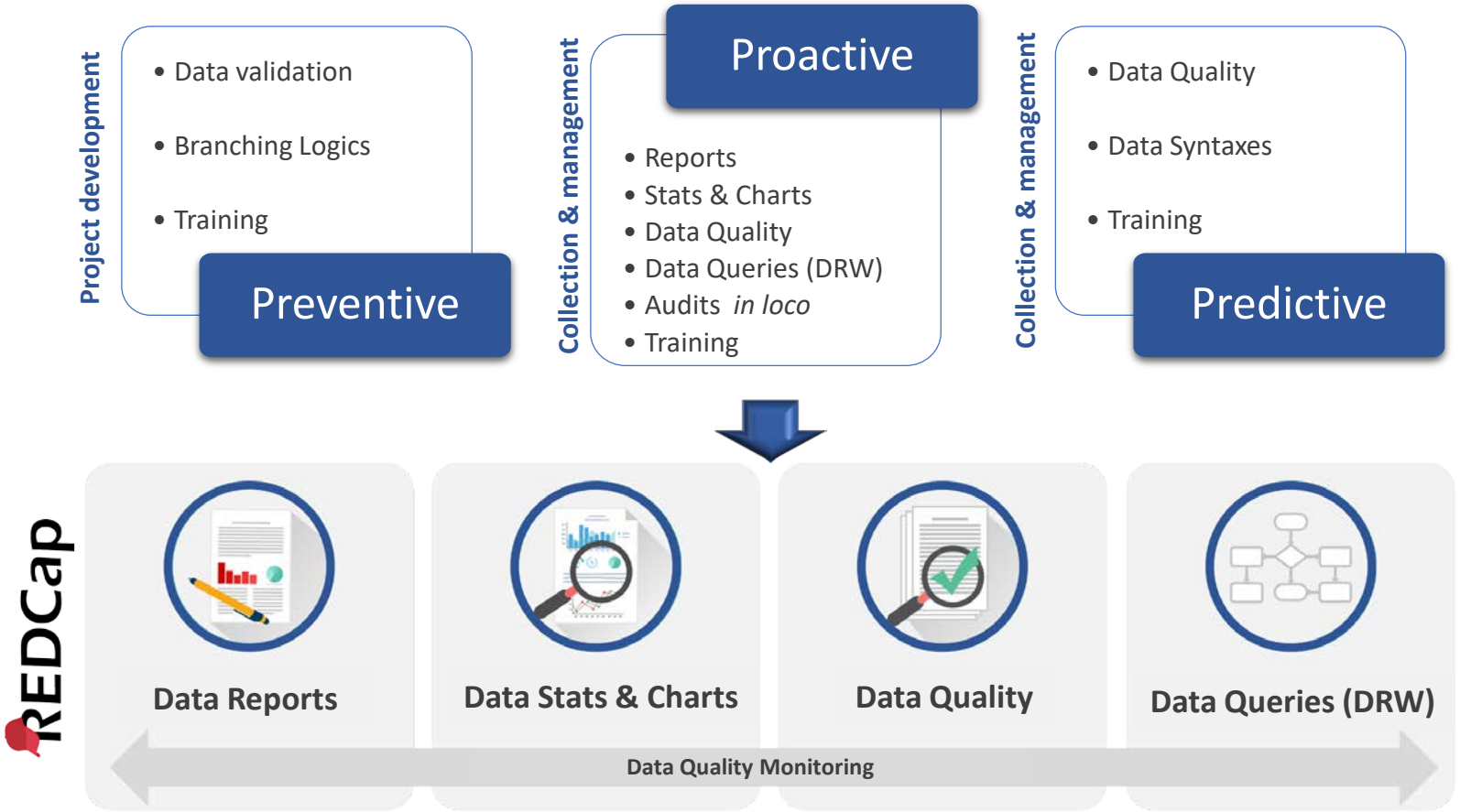
IMPLEMENTING A DATA MANAGEMENT INFRASTRUCTURE

STEP 4 – DATA INTEGRATION



IMPLEMENTING A DATA MANAGEMENT INFRASTRUCTURE

STEP 5 – DATA QUALITY MONITORING



CARDIAC PACING REGISTRY FRAMEWORK

OPEN ACCESS Freely available online

PLOS ONE

Glocal Clinical Registries: Pacemaker Registry Design and Implementation for Global and Local Integration – Methodology and Case Study

Kátia Regina da Silva[1,2]*, Roberto Costa[3], Elizabeth Sartori Crevelari[1], Marianna Sobral Lacerda[1], Caio Marcos de Moraes Albertini[1], Martino Martinelli Filho[4], José Eduardo Santana[5], João Ricardo Nickenig Vissoci[6,7,8], Ricardo Pietrobon[9], Jacson V. Barros[10]

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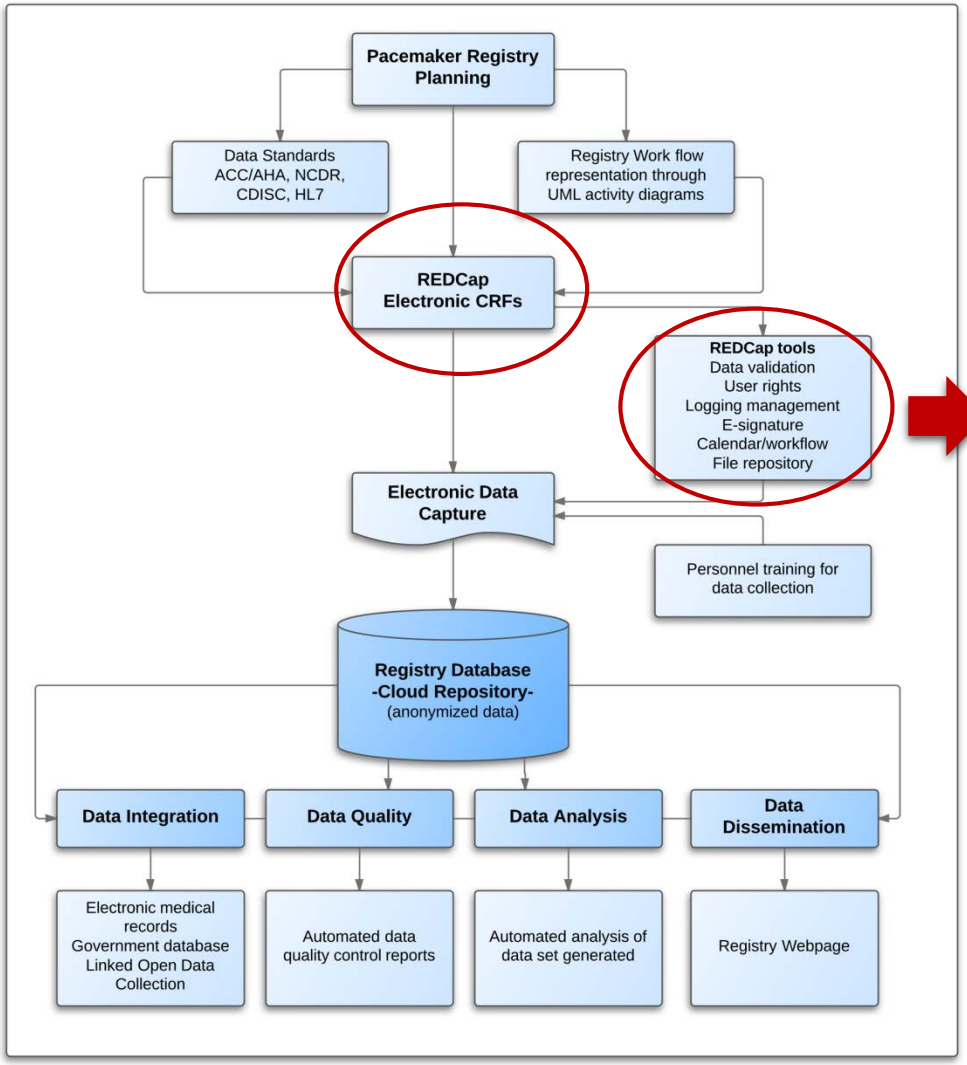
PLOS ONE 8(7): e71090. doi:10.1371/journal.pone.0071090

CARDIAC PACING REGISTRY FRAMEWORK



REDCap

PLOS ONE 8(7): e71090. doi:10.1371/journal.pone.0071090

CARDIAC PACING ADVERSE EVENTS PLATFORM

Developing an Adverse Events Reporting System to Measure Real-World Outcomes of Cardiac Implantable Electronic Devices

Katia Regina da Silva, Lucas Bassolli, Tatiana S. Kawauchi, Isabela C.M Amaya, Giovanna Melo, Jacson Barros, Igor Machado, Jose Mario Baggio, Clarissa Garcia Rodrigues, Guilherme Carvalho, Julio Cesar de Oliveira, Carlos Eduardo Batista de Lima, Martino Martinelli Filho, Roberto Costa

Heart Institute – São Paulo Medical School – University of São Paulo, Brazil & Research Center Collaborators

PURPOSE

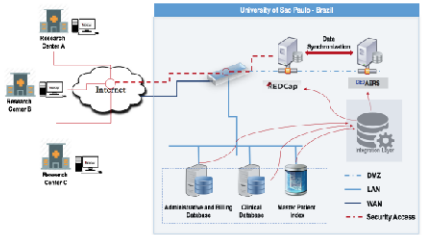
By using a web-based Adverse Events Reporting System (AERS) specifically designed to assess longitudinal CIED outcomes, we aimed:

To provide complete and validated data on complications, mortality and hospitalization within the first 12 months after CIED procedures.

METHODS

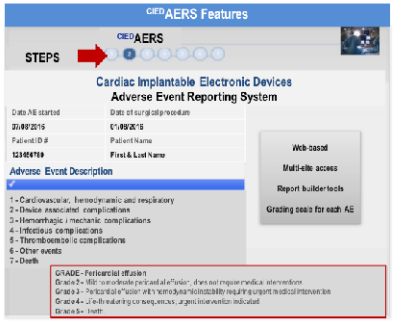
- **Settings**
  - Multicenter study: 9 cardiology centers
- **Study Population**
  - Subjects submitted to PM, ICD or CRT procedures
- **CIEDAERS Data Sources**
  - REDCap (Research Electronic Data Capture)
  - Electronic Health Records
  - Business Process Management (BPM) software
- **CIEDAERS Terminology**
  - MedDRA terminology
  - SNOMED-CT standardized cardiovascular vocabulary

Adverse Event Study Workflow

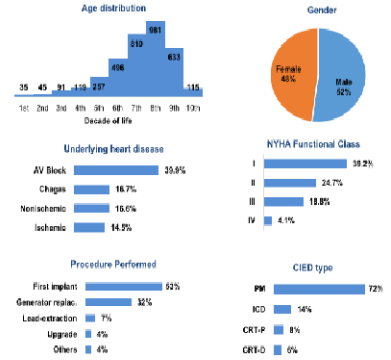


RESULTS

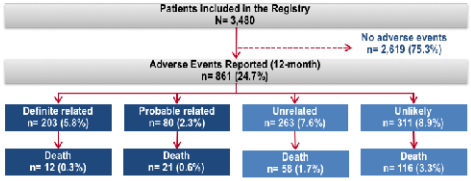
CIEDAERS Features



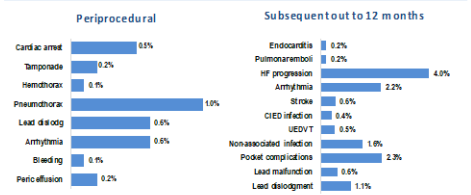
Baseline Characteristics — N= 3,480 patients



Summary of Adverse Events



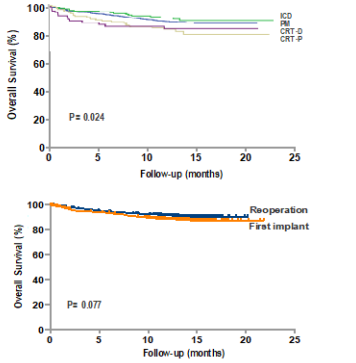
Adverse Events



Hospitalization

18.6% out of **3,480** patients had been hospitalized within the first 12 months

Mortality



Predictors for complications

Older Patients, NYHA FC IV, Presence of AF, Multiple Comorbidities, Ventricular Dysfunction, CRT-P, Reoperation Procedures (P<0.01)

CONCLUSION

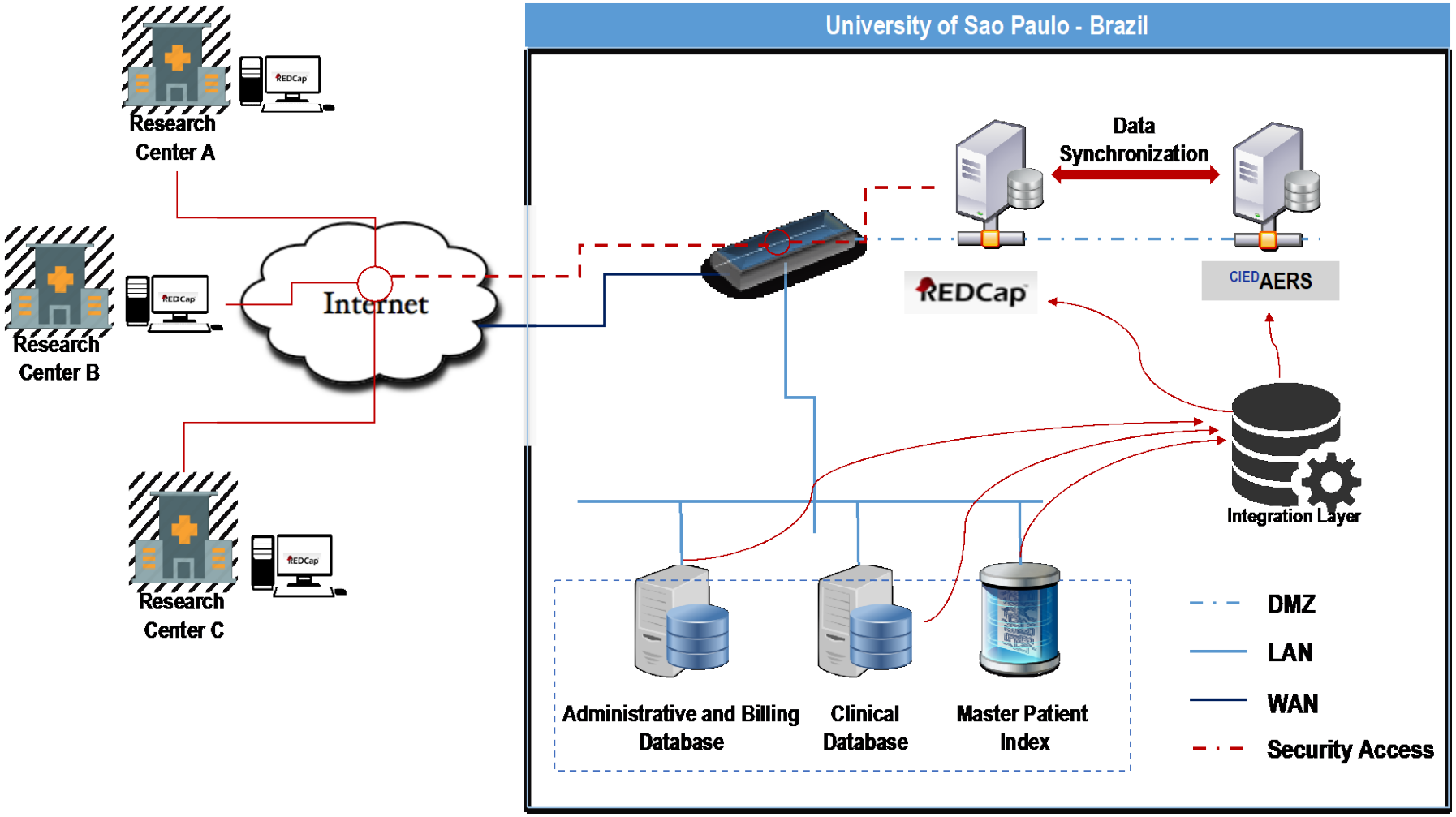
This Prospective Registry that included 3,480 patients followed-up by 12-months showed:

- **Complications rate was similar with previous studies**
  - 8.1% device-related
- **Re-hospitalization was frequent (18.5%)**
  - Main cause = HF decompensation
- **All-cause mortality was high (5.5%)**
  - 0.9% device-related
  - Higher in CRT-P patients
- **Clinical implications**
  - CIEDAERS is a flexible and suitable solution to perform the reporting and monitoring of adverse events in multicenter settings

Funding: CNPq/ REBRATS (Brazil Government Agency) – Grant Proposal # 401317/2013-7

Declaration of conflicts interest: The authors declare they have no conflicts of interest.

CARDIAC PACING ADVERSE EVENTS PLATFORM



CARDIAC PACING & REDCap: PUBLISHED PAPERS

Efficacy, Safety, and Performance of Isolated Left vs. Right Ventricular Pacing in Patients with Bradyarrhythmias: A Randomized Controlled Trial

Elizabeth Sartori Crevelari, Katia Regina da Silva, Caio Marcos de Moraes Albertini, Marcelo Luiz Campos Vieira, Martino Martinelli Filho, Roberto Costa

Instituto do Coração (InCor) do Hospital das Clínicas da Faculdade de Medicina da Universidade de São Paulo (HCFMUSP), São Paulo, SP – Brazil

Usefulness of preoperative venography in patients with cardiac implantable electronic devices submitted to lead replacement or device upgrade procedures

Caio Marcos de Moraes Albertini,[1] Katia Regina da Silva,[1] Joaquim Maurício da Motta Leal Filho,[1] Elizabeth Sartori Crevelari,[1] Martino Martinelli Filho,[1] Francisco Cesar Carnevale,[2] Roberto Costa[1]

Instituto do Coração (InCor) - Faculdade de Medicina da Universidade de São Paulo,[1] São Paulo, SP – Brazil

Hospital das Clinicas da Faculdade de Medicina da Universidade de São Paulo,[2] São Paulo, SP - Brazil

Minimally Invasive Epicardial Pacemaker Implantation in Neonates with Congenital Heart Block

Roberto Costa,[1] Katia Regina da Silva,[1] Martino Martinelli Filho,[1] Roger Carrillo[2]

Instituto do Coração (InCor) do Hospital das Clínicas da Faculdade de Medicina da Universidade de São Paulo,[1] São Paulo, SP – Brasil; University of Miami - Miller School of Medicine,[2] Miami - USA

CARDIAC PACING & REDCap: PUBLISHED PAPERS

Complications after Surgical Procedures in Patients with Cardiac Implantable Electronic Devices: Results of a Prospective Registry

Katia Regina da Silva, Caio Marcos de Moraes Albertini, Elizabeth Sartori Crevelari, Eduardo Infante Januzzi de Carvalho, Alfredo Inácio Fiorelli, Martino Martinelli Filho, Roberto Costa

Instituto do Coração (InCor) do Hospital das Clínicas da Faculdade de Medicina da Universidade de São Paulo (HCFMUSP), São Paulo, SP – Brazil

Functional Capacity of Patients with Pacemaker Due to Isolated Congenital Atrioventricular Block

Roberto Márcio de Oliveira Júnior, Kátia Regina da Silva, Tatiana Satie Kawauchi, Lucas Bassolli de Oliveira Alves, Elizabeth Sartori Crevelari, Martino Martinelli Filho, Roberto Costa

Instituto do Coração do Hospital das Clínicas da Faculdade de Medicina da Universidade de São Paulo (InCor/HCFMUSP), São Paulo, SP – Brazil

Quality of Life and Functional Capacity after Long-Term Right Ventricular Pacing in Pediatrics and Young Adults with Congenital Atrioventricular Block

KÁTIA REGINA DA SILVA, R.N., PH.D.,*,† ROBERTO COSTA, M.D., PH.D.,†
ROBERTO MÁRCIO DE OLIVEIRA JR., M.D.,‡ MARIANNA SOBRAL LACERDA, R.N.,§
ADRIANA I UN HUANG, R.N.,§ MARINA BERTELLI ROSSI, R.N.,§
ELIZABETH SARTORI CREVELARI, M.D.,† WAGNER TETSUJI TAMAKI, M.D., PH.D.,†
MARTINO MARTINELLI FILHO, M.D., PH.D.,¶ and RICARDO PIETROBON, M.D., PH.D.*

IMPLEMENTING A DATA MANAGEMENT INFRASTRUCTURE

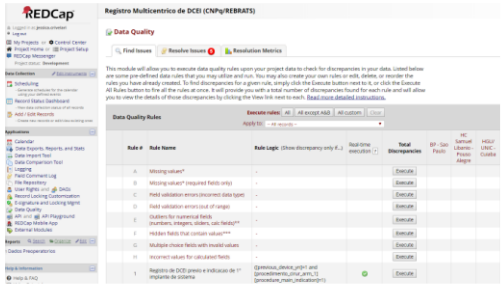
SCALABLE INFRASTRUCUTURE

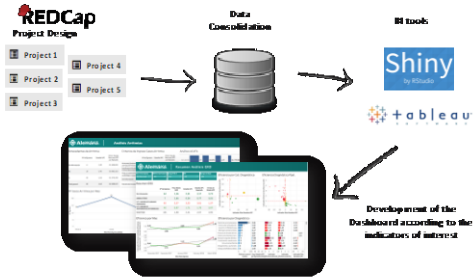
Data Acquisition | **Data Management** | **Data Analysis**

Hospital

Data collection at the point of care

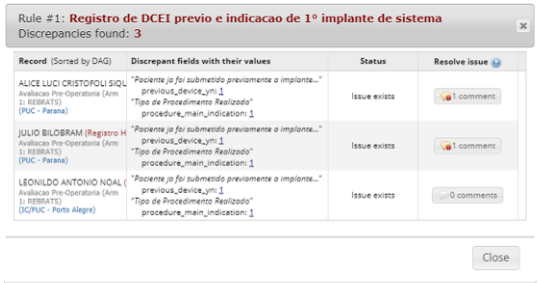
- Online
- Off-line

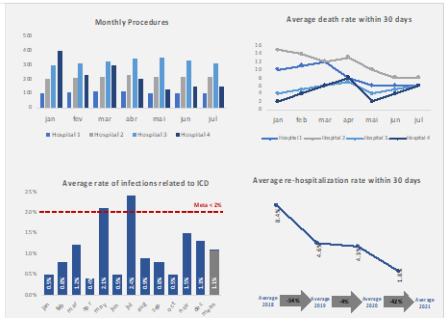




Home

- Survey
- Phone calls
- Twilio (soon)





CARDIAC PACING & REDCap

SCIENTIFIC CONTRIBUTIONS

More than 8,000 patients included in our studies

Streamlines process for collecting and managing data

Supports all research domains

Data Protection, Storage and Security

Increases Production

9 articles
15 projects
5 PhD thesis
5 research grants
53 presentations

CARDIAC PACING & REDCap

REDCap
Research Electronic Data Capture
BRASIL


SAVE THE DATE
April, 16 – 17, 2020
São Paulo, SP
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& Brazilian
REDCapCon