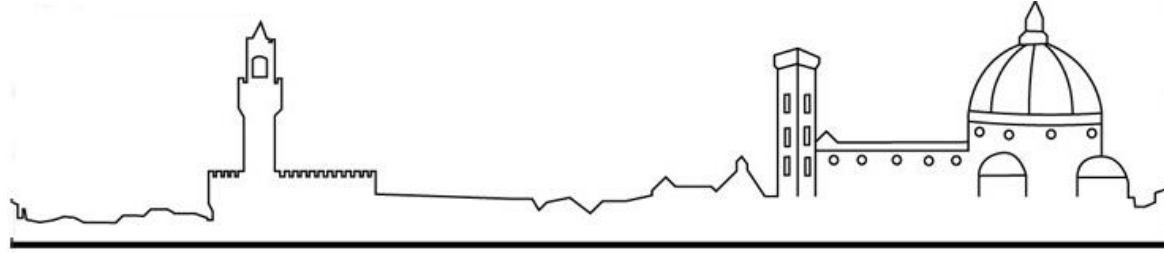


These presentations were developed by the respective presenter(s), and the findings, interpretations, and conclusions contained or expressed with them do not necessarily reflect the views of BD. To the extent these presentations relate to specific products, such products should always be used in accordance with the relevant instructions for use and other product documentation. This content should not be copied or distributed without the consent of the copyright holder. For further information, please contact: GMB-EU-MDS@bd.com



Azienda
Ospedaliero
Universitaria
Careggi

Tracking complications and adverse events

Fulvio Pinelli, MD

Careggi University Hospital

Florence, Italy

Dimension of the problem

- 6 million CVC inserted in US per year
- Over 15 million catheter days in US

ICU alone

Types and Impact of VADs Complications

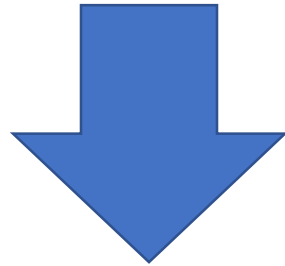
- Occlusion (38%)
 - CVAD failure
 - Treatment disruption
- Catheter related thrombosis (CRT)
 - 2-15%
 - Increased risk of PE (0-15%, depending on the location of CRT)
- Venipuncture related (33%)
 - Pneumothorax, hemothorax, multiple attempt, nerve/artery damage, air embolism, failure
- Catheter-related bloodstream infections (CRBSI)
 - 250k/yr in USA
 - Excess mortality (12% and 25%); 25,000 preventable deaths; economic burden (18000 €/episode; \$ 2 billion/yr)

Strategies To Reduce VADs Complications

- INTERNATIONAL GUIDELINES
- NATIONAL GUIDELINES
- LOCAL PROTOCOLS
- BUNDLES
- CHECKLISTS
- AUDIT, M&M
-

Do we track complications?

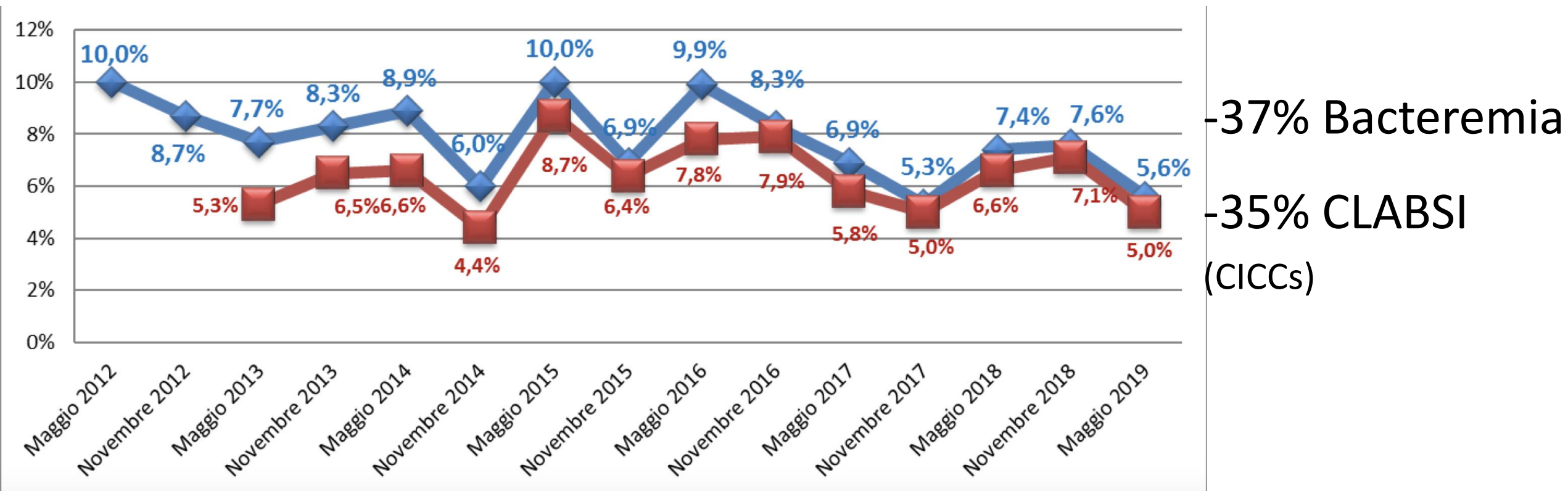
These strategies are not sufficient
without an effective and continuous
monitoring



TRACKING COMPLICATIONS

Which VADs Complications are Monitored?

- Hospital Infection Team
- Healthcare Associated Infections, every 6 months



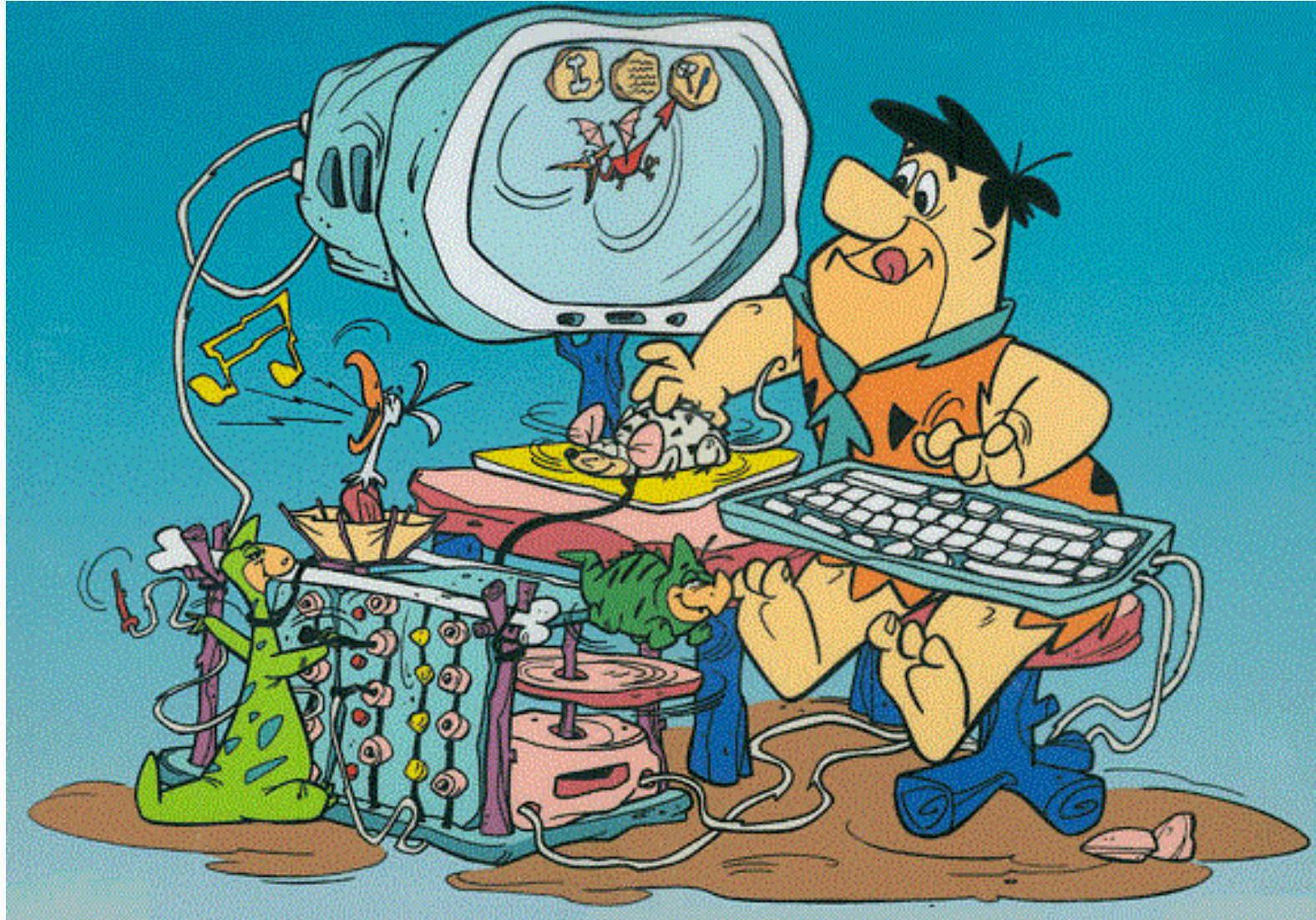
Limited informations, especially as vascular access specialists...

- Non-bacteremial complications:
 - venipuncture related, pocket infections, malpositioning, thrombosis, thrombophlebitis, displacement, malpositioning, failure, obstruction, etc..)
- Other VADs?
 - Medium and Long term VADs; PIVs; etc..



We Needed More...An IT Tool Able To:

- ❖ Track *ALL* major complications
- ❖ Dynamic and user friendly data manipulation
 - ✓ (research, surveys, statistics)
- ❖ Process analyses
 - ✓ Benchmarking
 - ✓ Proficiency
 - ✓ Feedbacks and corrections in behaviors
- ❖ Application of insertion and maintenance bundle (checklist)
- ❖ Decision support



***We had to
start
somewhere!***

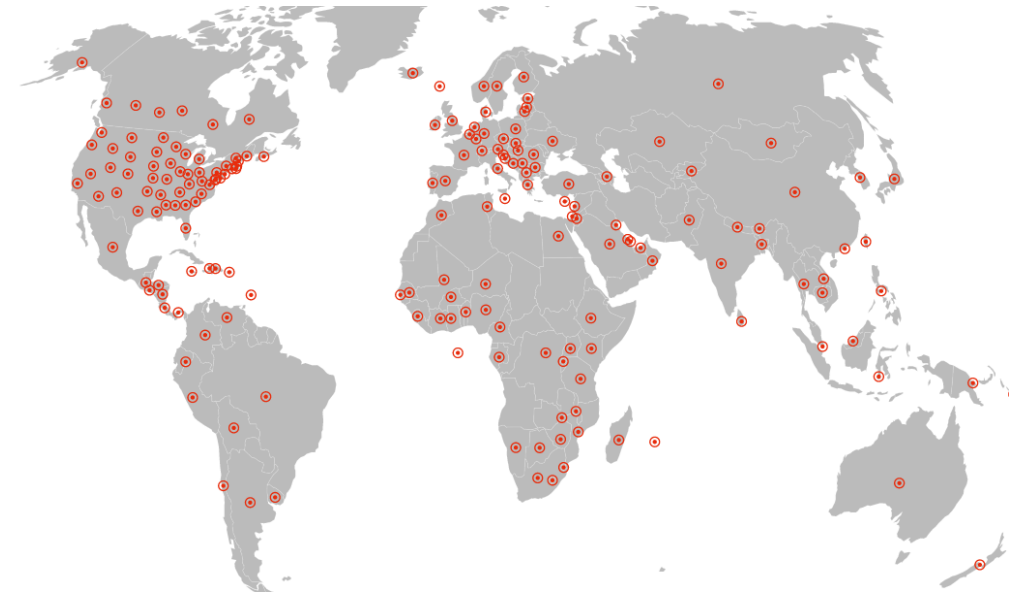


What is it?

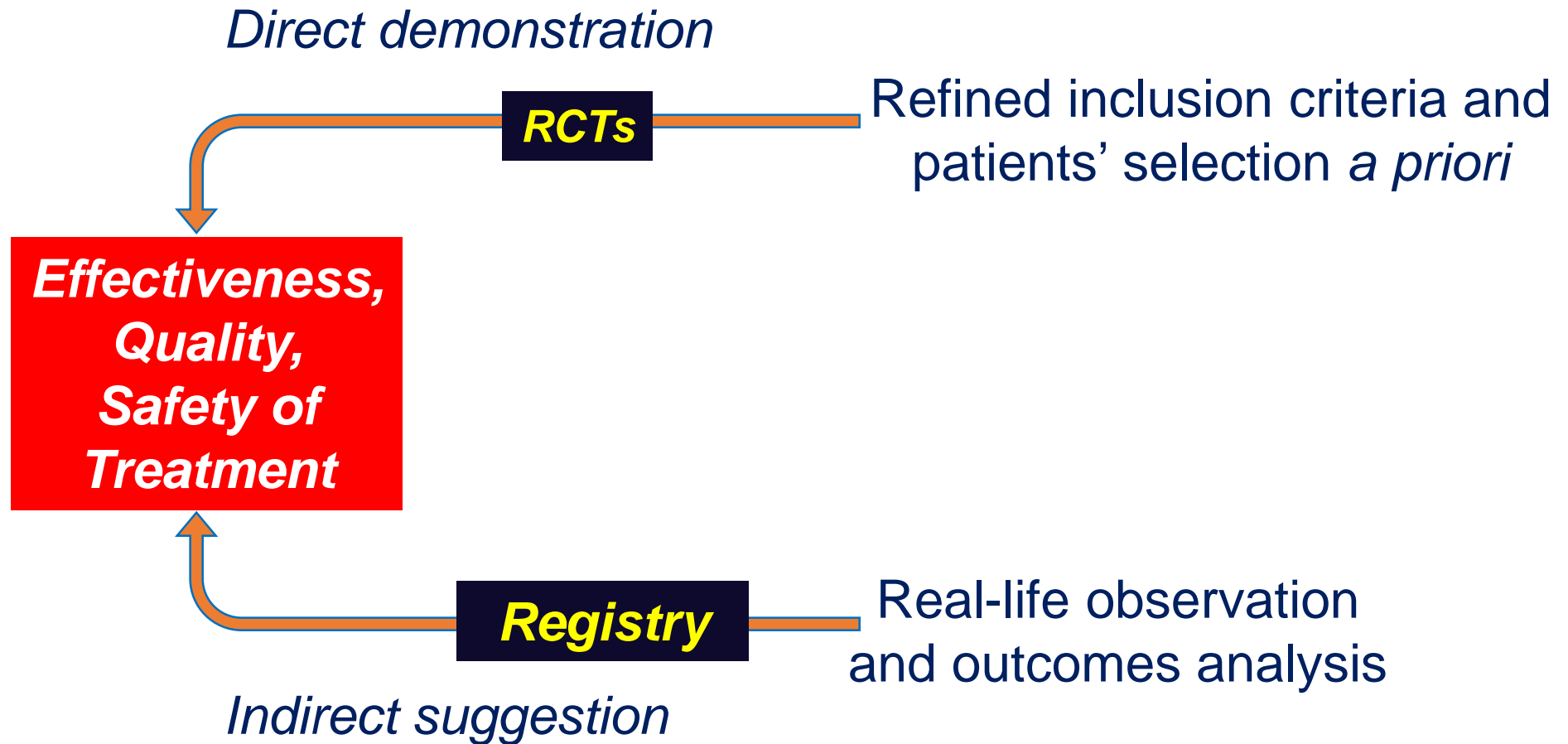
The REDCap™ (**R**esearch **E**lectronic **D**ata **C**apture) database is a registry adopted by **Careggi University Hospital** of Florence, Italy, and developed by **Vanderbilt University**.

To date the software is used **131 countries**, **3676 institutions** and is cited **7093 scientific articles**, becoming one of the **most widely used data collection tools** in the scientific world.

VANDERBILT  UNIVERSITY
MEDICAL CENTER

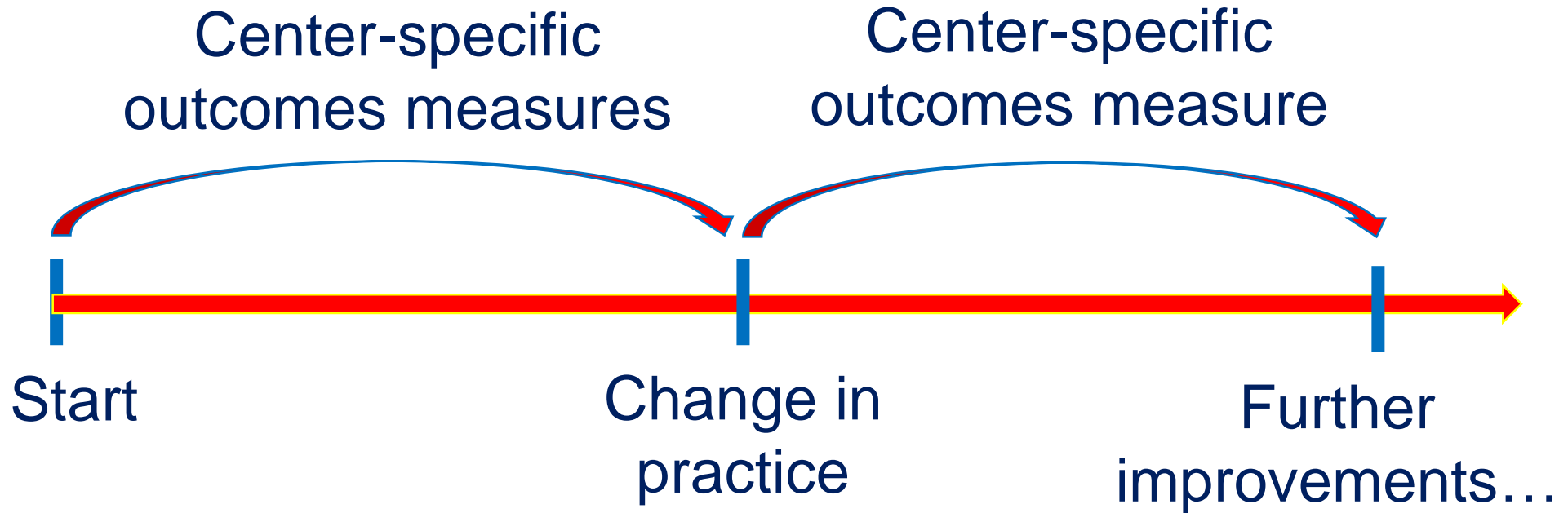


Clinical research has been changing



Center-specific Precision Medicine

Customizing treatment to specific center and sub-populations of patients



Medium and Long-term feedbacks



***Local Policies
Local Practices, etc.***

2 July 2019



*Centro Accessi Vascolari Database
Careggi University Hospital
Florence, Italy*

Platform Homepage

Record Home Page

Record "1" is a new Record ID. To create the record and begin entering data for it, click any gray s

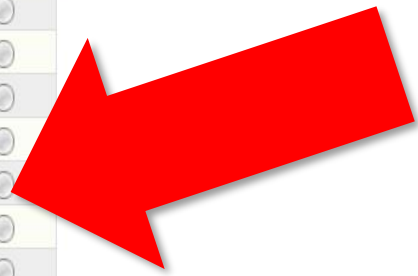
The grid below displays the form-by-form progress of data entered for the currently selected record. You may click on the colored status icons to access that form/event.

Legend for status i

- Incomplete
- Unverified
- Complete

NEW Record ID 1

Data Collection Instrument	Status
Anagrafica	<input type="radio"/>
Caratteristiche Accesso	<input type="radio"/>
Complicanze Intraprocedurali	<input type="radio"/>
Complicanze	<input type="radio"/>
Gestione Infermieristica	<input type="radio"/>
Termine	<input type="radio"/>
Followup Psicologo 1 Mese K Mammella	<input type="radio"/>
Complicanze 1 Mese K Mammella	<input type="radio"/>
Followup Psicologo 3 Mese K Mammella	<input type="radio"/>
Complicanze 3 Mese K Mammella	<input type="radio"/>
Followup Psicologo 6 Mese K Mammella	<input type="radio"/>
Complicanze 6 Mese K Mammella	<input type="radio"/>



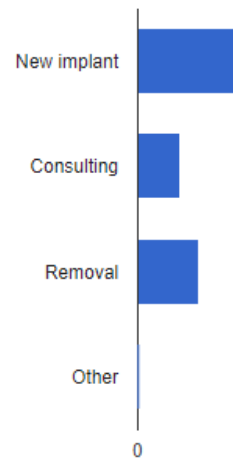
Data Collection Instrument	Status
Demographics	<input type="radio"/>
Procedure	<input type="radio"/>
Intraop Complications	<input type="radio"/>
Late Complications	<input type="radio"/>
Device Management	<input type="radio"/>
Removal	<input type="radio"/>
	<input type="radio"/>
	<input type="radio"/>
	<input type="radio"/>
	<input type="radio"/>
	<input type="radio"/>
	<input type="radio"/>

Type of activity, device, population, etc...

Reason for activation (*attivaz*) [Refresh Plot](#) | [View as Bar Chart](#) ▼

Total Count (N)	Missing	Unique
618	2 (0,3%)	4

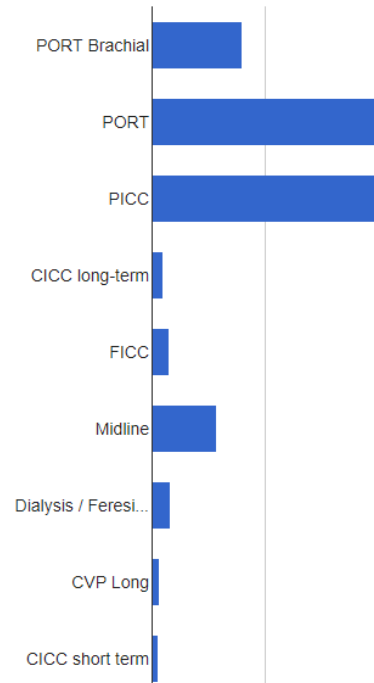
Counts/frequency: **New im**



Type of system (*tipo_impianto*) [Refresh Plot](#) | [View as Bar Chart](#) ▼

Total Count (N)	Missing	Unique
528	92 (14,8%)	9

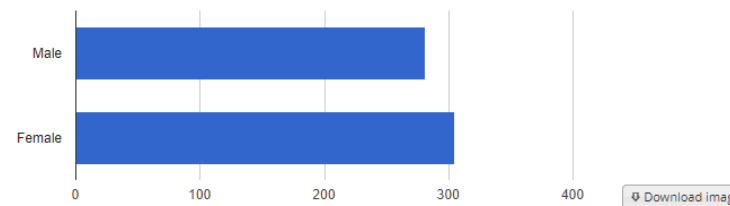
Counts/frequency: **PORT Brachial** (48, 9,1%), **PORT** (34, 6,4%), **Midline** (34, 6,4%), **Dialysis / Feresi catheter** (1, 0,0%)



Gender (*Sesso*) [Refresh Plot](#) | [View as Bar Chart](#) ▼

Total Count (N)	Missing	Unique
586	22 (3,6%)	2

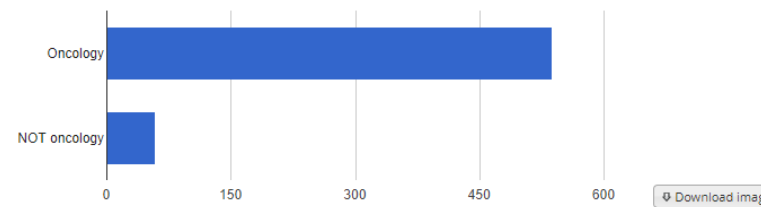
Counts/frequency: **Male** (281, 48,0%), **Female** (305, 52,0%)



Reasons for access (*indic_access*) [Refresh Plot](#) | [View as Bar Chart](#) ▼

Total Count (N)	Missing	Unique
596	12 (2,0%)	2

Counts/frequency: **Oncology** (538, 90,3%), **NOT oncology** (58, 9,7%)



Example: Early complications

- 61 (6,4 %) cases over 988
- Repeated puncture: 27
- Arterial puncture: 3
- Hematoma in venipuncture: 6
- Tip navigation / location failed: 5
- PNX: 0
- Pocket bleeding: 7

Example: Late complications

95/958 (9,91 %)

- Median days: 18
- Occlusion of the lumen: 6
 - Reversible: 4
 - Irreversible: 2
- CRT: 9 (8 symptomatic cases and 1 asymptomatic)
- Mechanical complication: 18
- CRBSI: 3

Immediate complication check

REDCap
Logged in as vittorio_bocciaro
Log out
My Projects or Control Center
Project Home or Project Setup
REDCap Messenger
Project status: Development

Data Collection / Edit Instruments
Record Status Dashboard
Add / Edit Records
Hide data collection Instruments: Anagrafica, Motivo accesso/impianto, Complicanze Intraoperatorie, Complicanze/Revisione, Gestione Infermieristica, Follow-up Psicologo e Complicanze - K Mammella, Termine percorso

Applications
Calendar
Data Exports, Reports, and Stats
Data Import Tool
Data Comparison Tool
Logging
Field Comment Log
File Repository
User Rights and DAGs
Record Locking Customization
E-signature and Locking Mgmt
Data Quality
API and API Playground
REDCap Mobile App
External Modules

Reports / Edit Reports

Azienda Ospedaliera Universitaria Careggi
Centro Accessi Vascolari

Data Exports, Reports, and Stats VIDEO: How to use Data Exports, Reports, and Stats
Create New Report | My Reports & Exports | Other Export Options | Stats & Charts: Complicanze

Number of results returned: 1320
Total number of records queried: 3723
View Report | Export Report | Print Page | Edit Report
Live filters: [Tipologia di impianto]

Complicanze

DISPLAY OPTIONS
Optional: Select a record to overlay onto the plots below -- select record --
Viewing options: Show plots & stats | Show plots only | Show stats only

Causale di intervento (complic_1) Refresh Plot | View as Bar Chart

Total Count (N)	Missing	Unique
117	4 (3,39%)	3

Counts/frequency: Complicanza rilevata (69, 59,0%), Revisione di complicanza (36, 30,8%), Consulenza (5, 4,3%)

Complicanza r... [Bar chart showing a single blue bar]

More important: clinician/registry interaction

LOCAL INFECTION

Yes
 No

reset

Localizzazione segni di infezione

Ex
 Tu
 Ta
 Gr

SISTEMIC INFECTION

Yes
 No

CLABSI

Yes
 No

Infezio
primar
cateter
dell'ins
dell'inf

CRBSI

Yes
 No

Yes
 No

Infezione ematica correlata al catetere. Criteri diagnostici:
Isolamento del medesimo microrganismo sia dal catetere che dal
prelievo di sangue periferico; Colture ematiche quantitative
simultanee con un tasso di microrganismi >5:1 provenienti dal CVC
rispetto al sangue periferico; Differenziale di tempo superiore a 2
ore di positività della coltura prelevata dal CVC rispetto alla
positività di quella prelevata dal sangue periferico

Stravasamento sottocutaneo

Yes
 No

reset

The system will help you in defining the complication, the severity and the further treatment strategy, using bundles, reminders, suggestions as a decision support tool.

Management

- View data collection status of all records

Add / Edit Records
- Create new record

Record ID
Domizio Poggiarelli

Save & Exit Form

Go To Next Form

STANDARDIZATION, HELPING DIAGNOSIS

Data Collection Instruments:

- Anagrafica
- Motivo accesso/impianto +
- Complicanze Intraprocedurali
- Complicanze/Revisione
- Gestione Infermieristica**
- Followup Psicologo K Mammella
- Complicanze K Mammella
- Termine percorso

Applications

- Calendar
- Data Exports, Reports, and Stats
- Field Comment Log
- File Repository
- User Rights
- REDCap Mobile App

Reports [Edit reports](#)

- 1) Tipologie di device
- 2) Prestazioni
- 3) consulenze

Help & Information

- Help & FAQ
- Video Tutorials
- Suggest a New Feature

Contact REDCap administrator





Record ID 948

Domizio Poggiarelli; 19-06-1949; giorno di [redacted] 2019; tipologia di impianto
CICC a breve termine; Fr: 5; Power Yes; Tunnel No;

INFORMAZIONI DI IMPIANTO

Hai palpato il sito di inserzione? Yes No

Immagine di riferimento Visual Exit-site Score (VES)

			
Score 0	Score 1	Score 2	Score 3
Cute sana, integra, senza segni di flogosi	Iperemia al punto di uscita del CVC < 1cm ² con o senza fibrina	Iperemia al punto di uscita del CVC compresa tra 1 e 2 cm ² con o senza fibrina	Iperemia, secrezioni e/o pus, con o senza fibrina

Sulla base dell'immagine precedente assegna lo score relativo VES

Yes No

Il paziente presenta SIRS Frequenza cardiaca superiore a 90 battiti al minuto; Temperatura

Decision support

- Create new records or edit/revise existing ones

Record ID: 1200
Prova Prova; 21-01-1967; inserimento: 10-01-2020
[Select other record](#)

Data Collection Instruments:

- Anagrafica
- Motivo accesso/impianto
- Complicanze Intraoperatorie
- Complicanze/Revisione
- Gestione Infermieristica**
- Follow-up Psicologo e Complicanze - K Mammella
- Termine percorso

Lock all instruments

Applications

- Calendar
- Data Exports, Reports, and Stats
- Data Import Tool
- Data Comparison Tool
- Logging
- Field Comment Log
- File Repository
- User Rights and DAGs
- Record Locking Customization
- E-signature and Locking Mgmt
- Data Quality
- API and API Playground
- REDCap Mobile App
- External Modules

Reports [Edit reports](#)

- 1) Tipologie di device
- 2) Prestazioni
- 3) consulenze
- 4) Complicanze
- 5) Bedside - Vigo

Help & Information

- Help & FAQ
- Video Tutorials
- Comment a New Feature

Nome e Cognome: **Prova Prova**, data di nascita: **21-01-1967**, sesso: **Maschio**

[Save & Exit Form](#)
[Save & Go To Next Form](#)
[Cancel](#)

Giorno di compilazione
14-01-2020 Today

INFORMAZIONI DI IMPIANTO
Prova Prova; 21-01-1967; giorno di i
10-01-2020; tipologia di impianto PORT Brachiale;
Fri 5; Power Yes; Tunnel Yes; [reset](#)

Il paziente presenta SIRS
Yes
No [reset](#)
Frequenza cardiaca superiore a 90 battiti al minuto; Temperatura corporea inferiore a 36 °C o febbre alta (> 38 °C); Aumento (tachipnea) o riduzione (bradipnea) della frequenza respiratoria; Numero di globuli bianchi nel sangue inferiore ai 4.000 per mm³ (leucopenia) o superiore ai 12.000 per mm³ (leucocitosi), oppure aumento superiore al 10% di forme immature di neutrofil.

il tunnel presenta
CONDIZIONE STABILE
Arrossamento
 Dolore
Indurimento
Ematoma
Altro

Consulta la procedura aziendale
[Watch video](#)

Cute circostante
CONDIZIONE STABILE
Lesione da cerotto
Arrossamento
Escoriazione
Altro

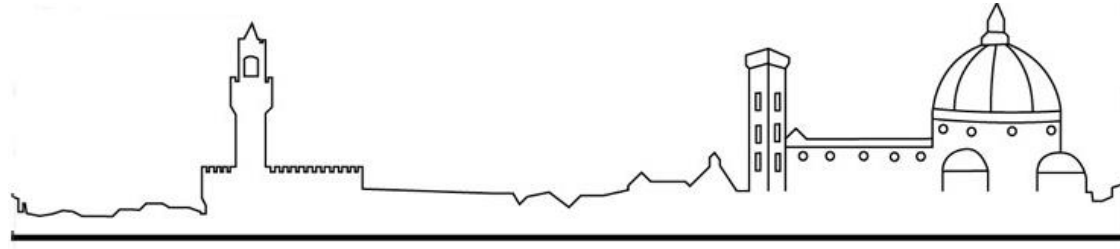
Condizione della tasca
CONDIZIONE STABILE
Discesa ferita
Ematoma
Necrosi
Dolore
Lesione di continuo
Eritema

CONCLUSION 1

- VADs complications have a **considerable impact** in terms of morbidity, mortality and costs
- **Tracking** is fundamental **part of a strategy** of complication reduction

CONCLUSION 2

- IT technology may not only helping us in tracking complications. The **platform-physician interaction** has additional useful effects on the single utilizing center:
 - Renewal of the concept of “clinical research”, which is focused to tailoring and customizing clinical choices (center specific precision medicine)
 - Provides center-specific clinical feedbacks;
 - Decision support;
 - Promotes good practice



Azienda
Ospedaliero
Universitaria
Careggi

THANK YOU

Fulvio Pinelli, MD
Careggi University Hospital
Florence, Italy