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# Principles leading the design of the RIPI Information System: an example of a multi-level registry structure for different medical devices

**Veronica Mari[1], Simona Pascucci[1], Eugenio Carrani[1], Duilio L. Bacocco[1,2], Riccardo Valentini[1,2], Paola Ciccarelli[1], Saif A. Madi[1,3], Marina Torre[1]**

[1] Scientific Secretariat of the Presidency, Italian national Institute of Health, Rome, Italy
[2] Department of Computer, Control and Management Engineering, "Sapienza" University of Rome, Rome, Italy
[3] Department of Computer Science, "Sapienza" University of Rome, Rome, Italy

## Introduction

The Italian Implantable Prostheses Registry (RIPI) is a multi-level registry system assessing several implantable medical devices in terms of effectiveness and safety and tracing them for post-market safety-related activities. This study aims at presenting the concepts in designing the RIPI Information System (RIPI-IS).

## RIPI structure

RIPI is coordinated by the Italian National Institute of Health as established by the Governmental Decree issued in 2017 (DPCM).
RIPI currently covers joint prostheses (RIAP), spinal implants (RIDIS), pacemakers and defibrillators (RIDEP), hearing implants (RIDIU).
Preliminary activities for a craniofacial implants registry (RICRAF) have been undertaken. The registry for artificial heart valves (RIVAC) is currently in stand-by (Figure 1).

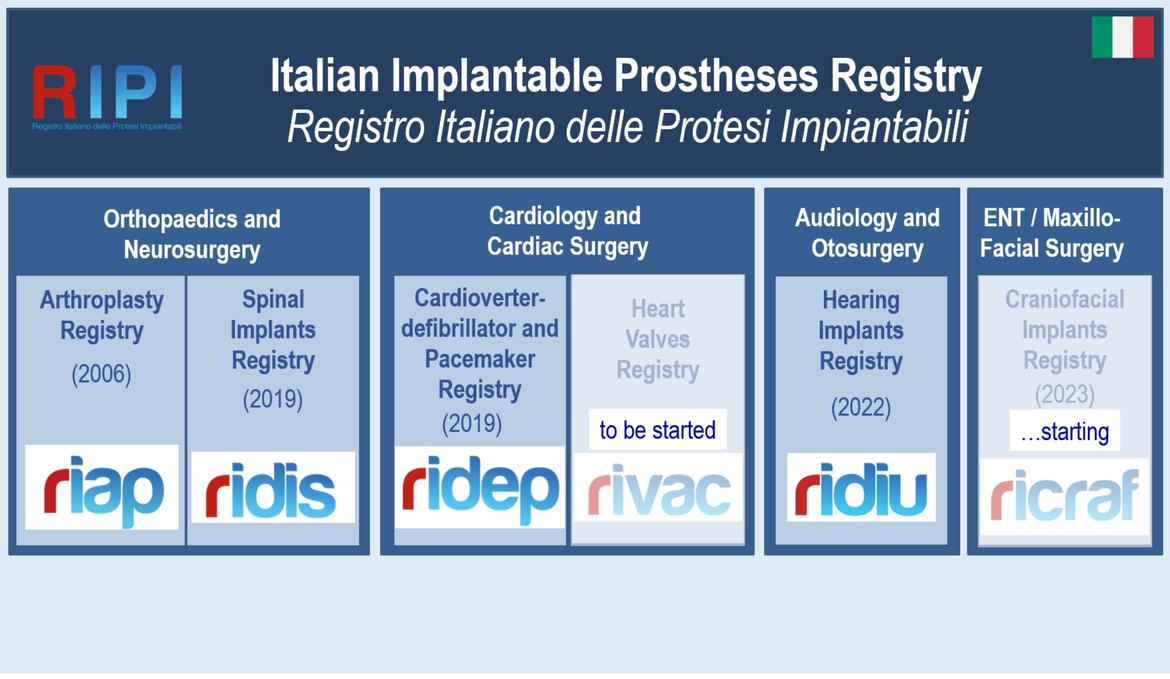


Figure 1: The structure of RIPI, an implantable prostheses registry able to collect data for all the implants performed in Italy.

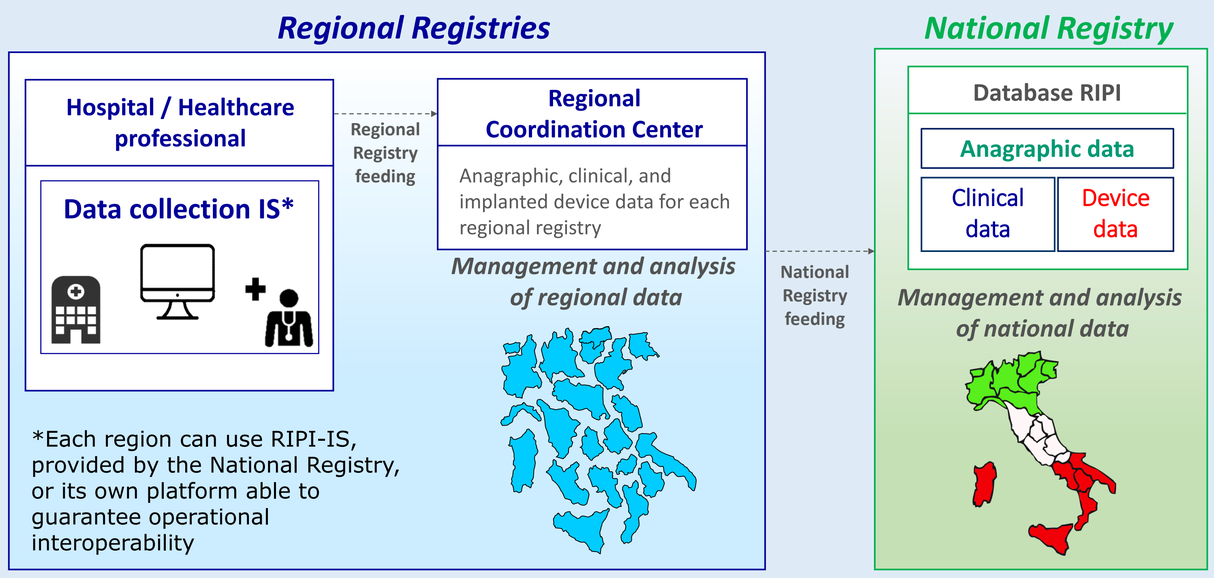


Figure 2: RIPI-IS reflects the structure of the Italian health care system, where each hospital belongs to a regional system, with autonomous characteristics but still part of a national system.

## Materials and methods

RIPI-IS design was based on the following pillars:

1 - each national registry included in RIPI (specific for a medical device) is organized as a federation of regional registries reflecting the fragmented structure of the Italian health care system where each region is autonomous in managing its own regional health care system.

2 – common principles to be implemented by each region are defined to guarantee operational interoperability.

3 – both GDPR and traceability requirements are met: the patient is pseudonymized with a unique code throughout the country and in the several registries included in RIPI.

## Results

The modular structure adopted for RIPI-IS allows to consolidate established registries, such as RIAP (arthroplasty), and to easily integrate any additional one.

Each registry is characterized by specific variables, which can be chosen, collected and managed independently, and by variables in common with all registries, which need to be determined at a higher level (RIPI level) by a scientific committee.

To collect data, each region can decide either to use the national platform, provided at central level by ISS, or to implement its own system by following the shared common principles (Figure 2).

Throughout the country, the unique patient code allows to trace patients and implanted devices in order to overcome issues related to inter-regional mobility (Figure 3).

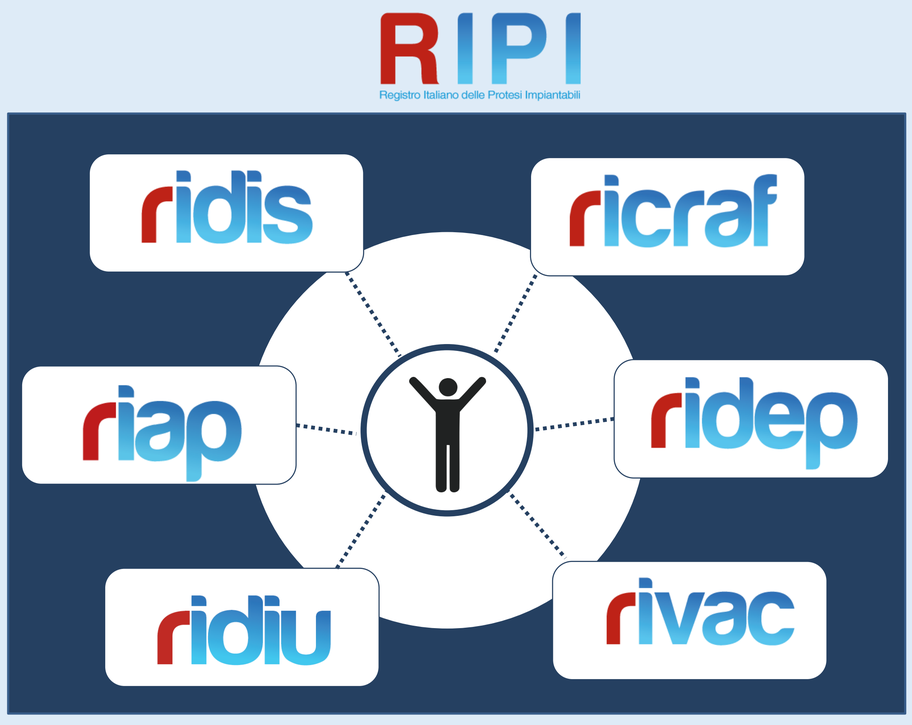


Figure 3: The patient is characterized by a unique pseudonym for all RIPI registries.

## Discussion

The modularity of the structure and the scalability of the system allow to optimize data collection and the information available to surgeons, regions and policymakers.
The definition of common principles led to the standardization of registry procedures, thus ensuring patient safety in a complex health context lacking homogeneous features, such as the Italian one.
The methodology designed to manage national and regional registries in Italy might be considered a useful experience to be exported to broader and international contexts.

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