

# The modularity of RIPI: a common infrastructure of independent but connected registries

Veronica Mari<sup>1</sup>, Eugenio Carrani<sup>1</sup>, Duilio Bacocco<sup>1</sup>, Simona Pascucci<sup>1</sup>, Michela Franzò<sup>2</sup>, Attanasio Cornacchia<sup>1</sup>, Marina Torre<sup>1</sup>

<sup>1</sup> Scientific Secretariat of the Presidency, Italian national Institute of Health, Rome, Italy  
<sup>2</sup> Department of Mechanical engineering, La Sapienza University of Rome, Rome, Italy

[veronica.mari@iss.it](mailto:veronica.mari@iss.it)

## Introduction

Starting from the positive experience of RIAP and RIDIS, Italian Arthroplasty and Spinal Implant Registries, a multi-registry system (RIPI) has been created to assess various implantable medical devices (IMDs) in terms of effectiveness and safety and to trace them for post-market safety-related activities.

## RIPI structure

RIPI is coordinated by the Italian National Institute of Health as established by the DPCM approved on March 3, 2017. RIPI currently involves joint prostheses (RIAP), spinal implants (RIDIS), pacemakers and defibrillators (RIDEP). Preliminary activities for a hearing devices registry (RIDIU) have been launched. Soon we plan to start the registry for artificial heart valves (RIVAC) as well.



Figure 1: The structure of RIPI, an implantable prostheses registry for data collection of all the implantable prostheses procedures performed in Italy.

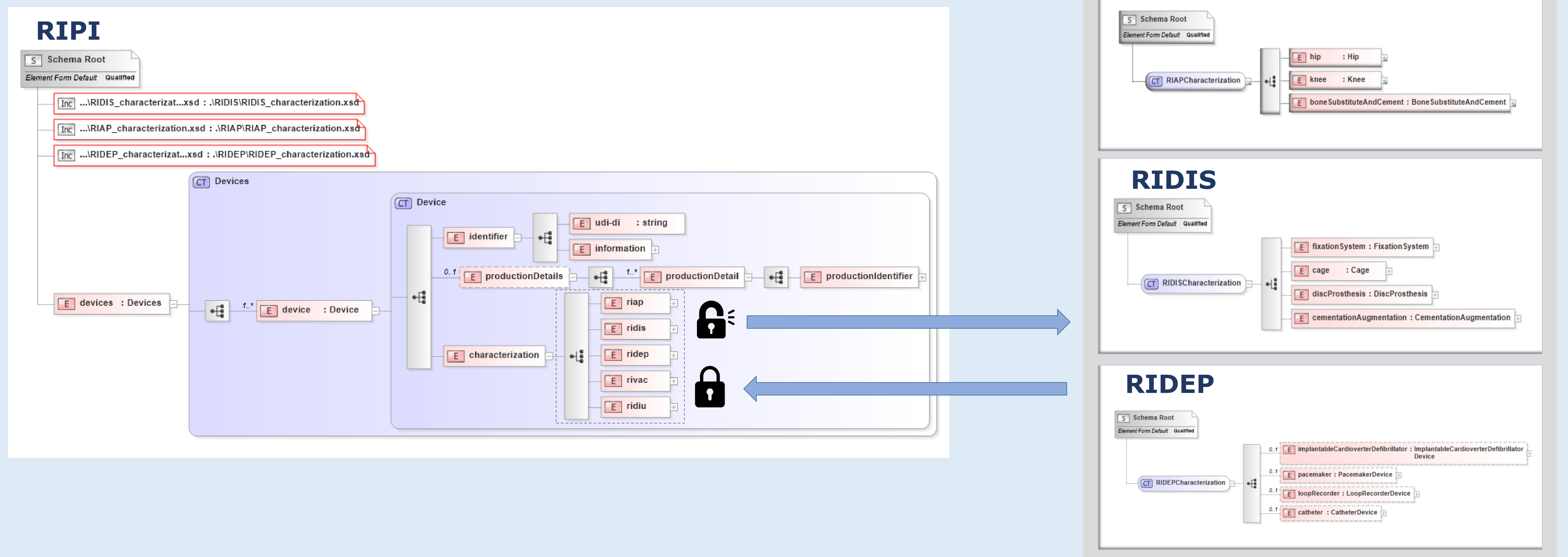


Figure 2: An example of how the overall structure of RIPI covers that of individual registries in a decoupled way, allowing individual registries to carry out independent evolutions.

## Materials and methods

Since each registry initially had a separate infrastructure and was jointly managed by ISS (RIPI research group), we decided to take advantage of RIPI's overall role.

Data were modeled according to the rules given by Extensible Markup Language (XML) for their formal representation.

Following the principles of the software engineering, we renovated the informatic structure to decouple data relevant for all the registries from data completely registry-dependent.

It has been realized by designing separated registry-dependent XSD schemas for each registry, common schemas for regulatory aspects and shared variables, and by allowing access to the external and registry-dependent XSD schemas into the RIPI XSD schemas.

## Discussion

Thanks to this renovation, RIPI appears to be an essential connector for all the specific registries, because each registry has an independent management, but its results are meaningful only if included into RIPI.

The strategy of decoupling common data from the specific ones gives RIPI a more

## Results

RIPI has become not just a mere grouping of registries, but has its own unique structure that covers the features in common to all the IMDs, allowing them to be compliant to regulatory requirements and able to trace devices and patients.

Any mandatory upgrade can be applied involving RIPI only: specific registries can undergo any modifications related to the IMDs they cover, according to market evolution or to the clinical variables that need to be collected, without touching any parts of the general RIPI source code.

modular structure. This implies a less management effort and permits to easily add other new registries and enrich data collection in a more immediate way.

In the near future, the design of RIDIU and RIVAC, or any new registry, will be smarter and streamlined.