Finanziato dall'Unione europea NextGenerationEU
Ministero dell'Università e della Ricerca
Italiadomani PIANO NAZIONALE DI RIPRESA E RESILIENZA
ROME TECHNOPOLE INNOVATION ECOSYSTEM

ISS RIPI/RIAP, BVTech, Confindustria Dispositivi Medici and the National Joint Registry (NJR) meeting

Implementation of the MD identification and characterization dataflow for joint prostheses within the π-RIPI project and its interconnection/interoperability with the NJR Component Database

Istituto Superiore di Sanità, Rome - May 15 - 16, 2025

RIAP interconnection with CDB: how it works and its benefits for π-RIPI project

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π-RIPI Piattaforma - Registro Italiano delle Protesi Impiantabili

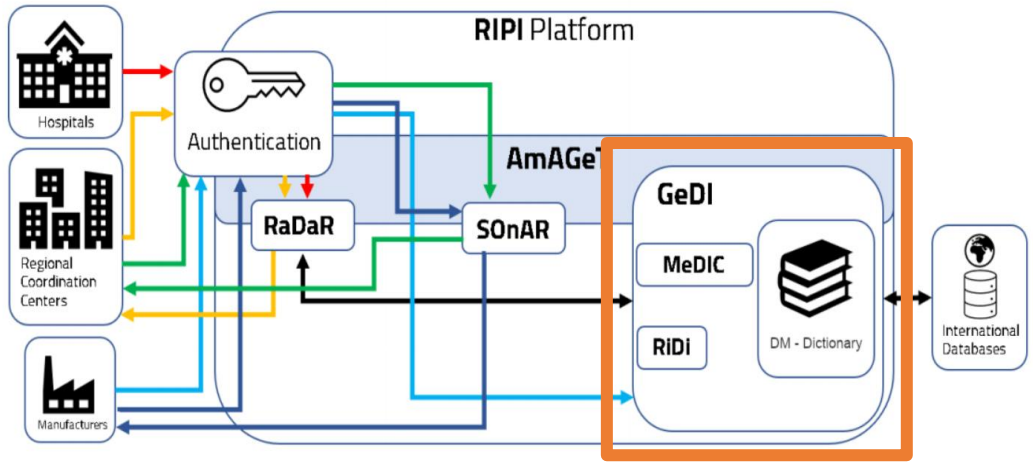
GeDI: Manager of the Dictionary of Implantable Devices

It is accessed by users:

- through graphical user interfaces (GUIs);
- by invoking specific APIs.

It will also be capable of interoperating in a cooperative manner with external entities through externally exposed APIs:

- at the national level;
- at the international level;



The implementation of this module enables:

- An innovative feature for device management and updates;
- Application-level integration with external systems;
- AI-based retrieval of medical device data from official online sources.

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GeDI: Manager of the Dictionary of Implantable Devices

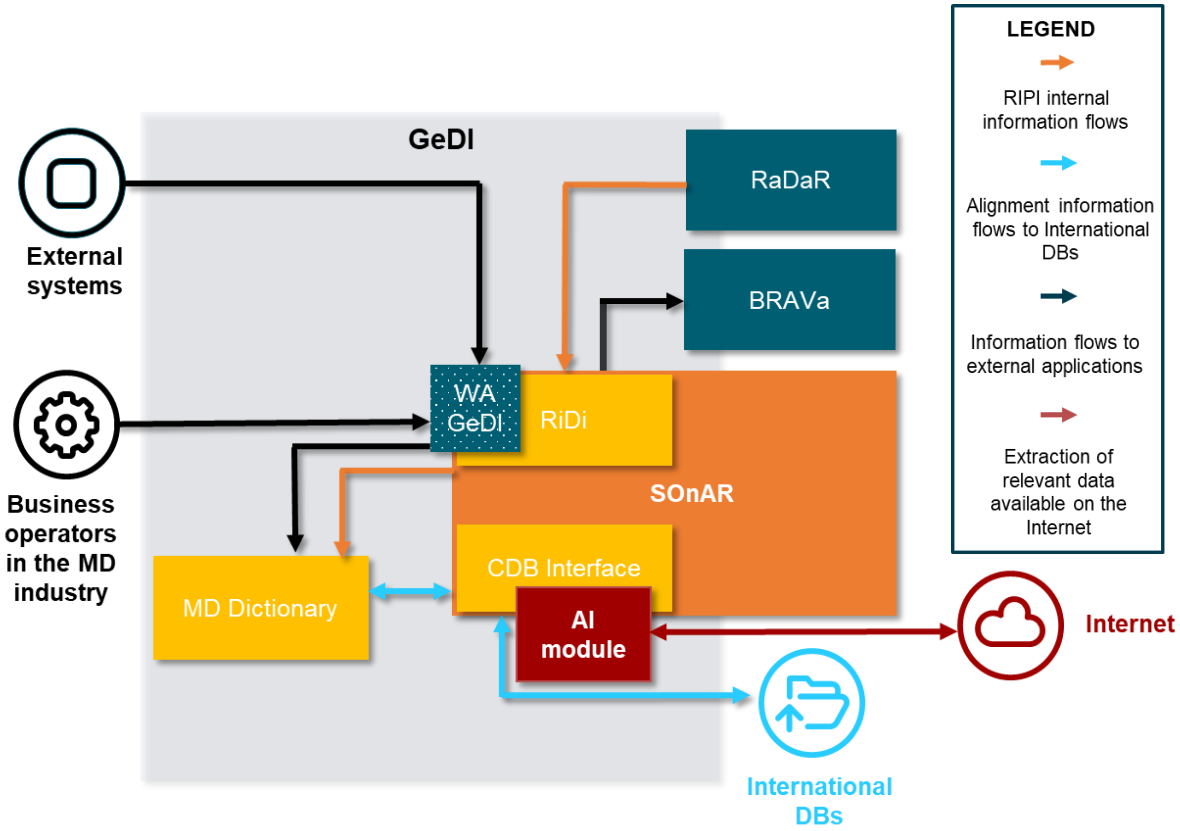
GeDI allows access to the Dictionary (Through WebAPP and A2A Integration (APIs)):

through the **RiDi Web Service**:

- *Internally*: it is used by RaDaR to choose devices implanted in surgeries
- *Externally*: Access to and updating of the platform dictionary of implantable devices by business operators in the medical device industry

through the **interoperability endpoints**:

- *Externally*: Access to and updating of the platform dictionary through integration international institutions



π-RIPI Piattaforma - Registro Italiano delle Protesi Impiantabili

ISS-NJR Agreement

Purposes:

- Create a single shared database of orthopedic prostheses
- Enable RIAP and its affiliated registries to access the Component Library in order to link each device to the relevant attributes for its complete description
- Allow manufacturers to contribute to the Component Library by providing data on devices not yet catalogued but already implanted and recorded by registries in other countries

National Joint Registry
www.njrcentre.org.uk
Working for patients, driving forward quality

HQIP
Healthcare Quality Improvement Partnership

This licence is dated [June 10, 2021]

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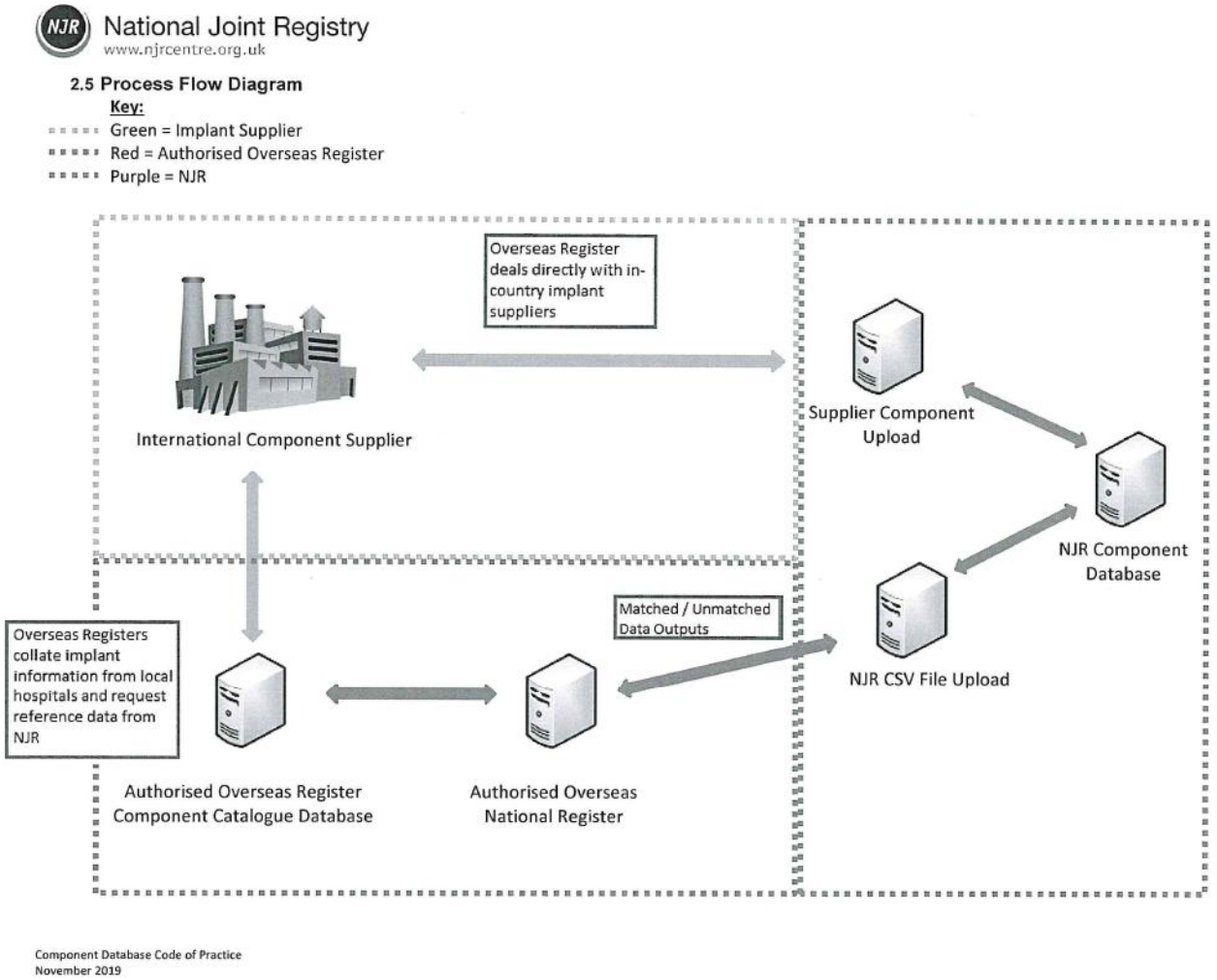
ISS-NJR Agreement:
Data collection flow Standard

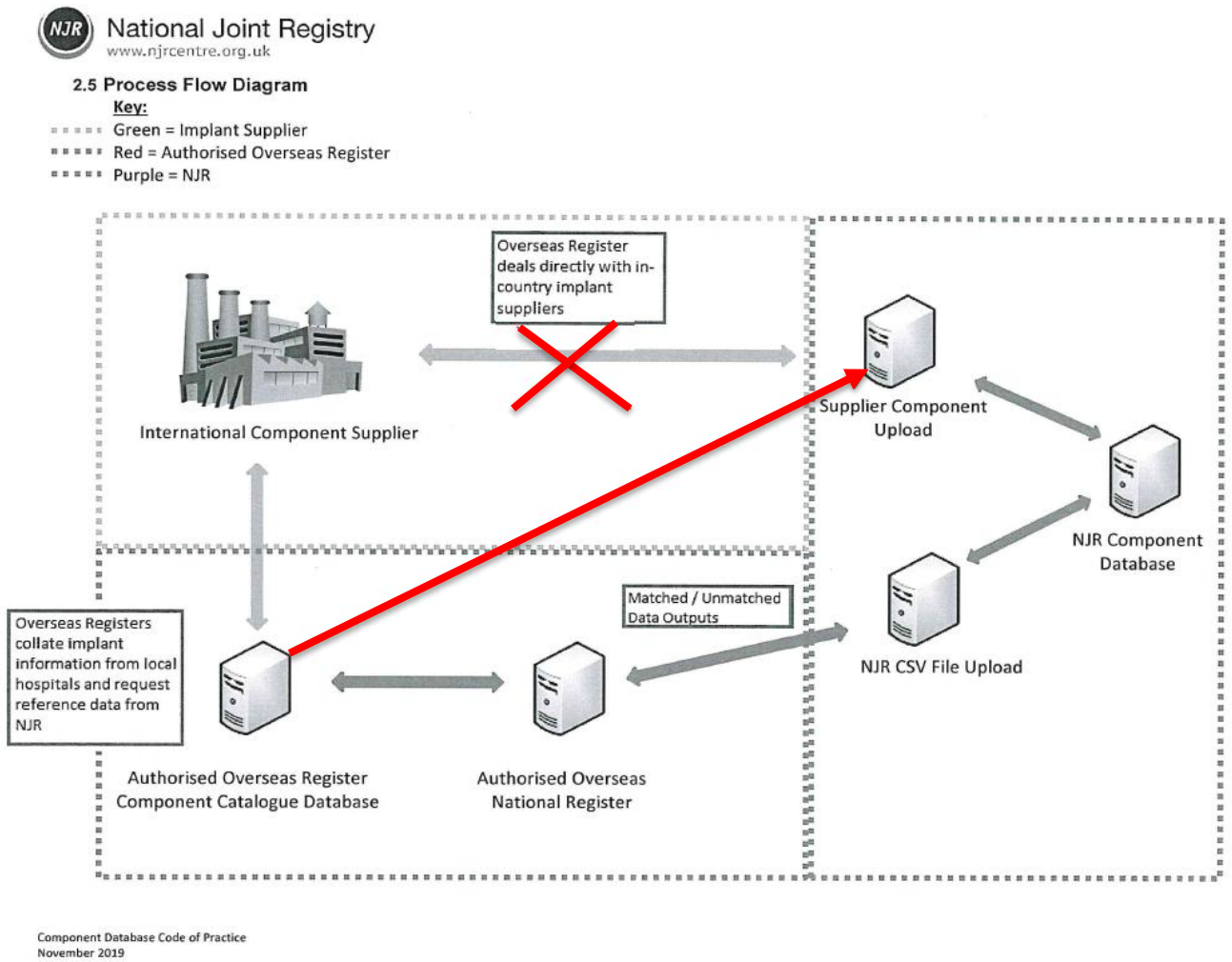
Linkage with CDB to obtain additional characteristics of the Medical Device present in the local registry:

- *Data for exact match*: manufacturer name and catalogue number or manufacturer name and GTIN
- *Matched data*: sharing uptaded of the submitted medical device data
- *Unmatched/Partial matched data*: Requires manual request by the manufacturer, with the entry of the minimum data required by CDB for the joint type implant.



ISS-NJR Agreement:
Data collection flow modified for RIPI

The manufacturer is not required to upload data directly to the CDB, the data will instead be submitted to the local registry, and our system will be responsible for transmitting the information to the CDB.



GeDI: Current Status – Features Implemented

User role implemented:

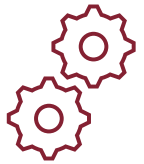
- **Administrator:** full read and write access to all medical devices
- **Manufacturer:** management of their own company's devices only
- **Participant:** read-only access to any manufacturer's medical devices

Functionality	Administrator	Manufacturer	Participant
Full MD Dictionary reading	✓	X	✓
Reading own devices	✓	X	✓
Device entering/updating	✓	✓*	X
Detection management	✓	X	X

* Only for own company devices

GeDI: Current Status – Features Implemented

- **Device Management Capabilities:**



1. **Manual Device Entry**
   Web interface for entering single devices
   Updating device records enhanced in the MD Dictionary
2. **Massive Uploading**
   Upload of XML files containing multiple devices
   Validation performed through the BRAVA module (currently implemented as a stub)
3. **API Integration for detection**
   Receiving detection of missing devices
   Management of the approval/rejection workflow for submitted detection
4. **A2A (Application-to-Application) Integration**
   Automated receipt of XML files for device upload
   Authentication system using API keys for manufacturers
   Automated Communication with External Systems

GeDI: Current Status – Features Implemented

- **Validation and Error Handling Workflow:**
  Integration for XML validation through BRAVa
  Error reporting in XML format for A2A communications
  Error reporting in XLSX format for interactions via the webAPP

- **Authentication and Authorization System**
  Authentication via an external Identity Provider (currently a local Keycloak instance)
  AMAGET service (currently a stub) for assigning claims
  Authentication tokens with claims for controlled access to functionalities

GeDI: Components under development for information sharing RIAP-CBD

1. Technical definition for communication with NJR
2. API formats and methods;
3. CBD interface technical design;
4. Technical data definitions for medical device component entities;
5. Technical protocols for managing NJR classification updates.