



KNOWLEDGE GAINED

SPEs have different features such as software and data collection tools.

KEY MESSAGE

SPE is an important part of RWE studies and clinical trial extensions.

European Health Data Space (EHDS) Requires Secure Processing Environments (SPEs) – Comparison of SPESiOR to Other SPE-Type Environments from Finnish, Nordic, European, and Global Settings



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OBJECTIVE

- The European Health Data Space (EHDS) is designed to make health data more accessible to improve health, research, knowledge management, and innovation for all in Europe.
- Real-world data (RWD) sharing for secondary use purposes under the EHDS requires high security protocols. Key issues tackled include data privacy, data integration from multiple data controllers, and data governance.
- In practice, the EHDS requires so-called secure processing environments (SPEs), which provide strong technical and security safeguards based on standards.
- We compared the features of different SPE-type environments available to SPESiOR® (<https://esior.fi/en/spesior/>), an SPE-type environment developed originally for health economics and outcomes research as well as chart reviews and dashboard modelling in Finland.

METHODS

The methods of the evaluation are summarized in the table below using the PICOSTEPS framework (Table 1).¹ Comparison of other SPE-type environments was done against the first private certified secure operating environment SPESiOR® using information available from their websites in September 2023.

Table 1. Summary of evaluation framework.

PICOSTEPS ⁶	Definition of method
Population (subjects of evaluation)	Secure processing environment (SPE) –type environments.
Intervention (new technology)	SPESiOR by ESiOR Oy, Kuopio, Finland (https://esior.fi/en/spesior/).
Comparators	Finnish, other Nordic, other European, and other than European SPE-type environments.
Outcomes	Ownership, included software and use of own software, additional data collection possibilities, operational reliability, customer service and its speed, technical requirements such as fixed IP address, possibilities to use outside the providing organization, and having both Windows and Linux virtual machines.
Setting	Public information in provider organization (manufacturer) websites.
Time	September 2023.
Effects	Proportion of systems with the evaluated features based on their websites.
Perspective	SPE user.
Sensitivity analyses	None considered.

RESULTS

- Comparison included 17 SPE-type environments (53% certified Finnish, 24% other Nordic, 12% other EU-based, and 12% non-EU environments) in total. (Tables 2 and 3).

Table 2. Comparison of Finnish SPE-type environments.

Features	SPESiOR	SPE1	SPE2	SPE3	SPE4	SPE5	SPE6	SPE7
Privately owned	✓	–	–	–	–	–	–	–
More software can be added	✓	?	✓	✓	–	–	✓	✓
Integrated data collection tool	✓	–	–	–	–	–	–	–
Operational reliability	✓	?	?	?	?	?	?	?
Fast customer service	✓	?	?	?	?	?	?	?
No fixed IP address needed	✓	–	–	–	–	–	–	–
Can be accessed by users outside the organisation	✓	✓	–	–	✓	–	–	–
Both Windows and Linux VM	✓	–	–	–	–	–	–	–

Table 3. Comparison of other than Finnish SPE-type environments.

Features	Nordic 1	Nordic 2	Nordic 3	Nordic 4	EU 1	EU 2	Non-EU 1	Non-EU 2
Privately owned	–	–	–	–	–	–	–	–
More software can be added	–	✓	–	✓	✓	–	✓	✓
Integrated data collection tool	–	–	–	–	–	–	–	–
Operational reliability	?	?	?	?	?	?	?	?
Fast customer service	?	?	?	?	?	?	?	?
No fixed IP address needed	?	?	?	✓	?	?	–	–
Can be accessed by users outside the organisation	✓	–	–	✓	*	?	–	–
Both Windows and linux VM	–	–	–	–	–	–	–	–

- SPESiOR alone was reported as privately developed and owned environment, had customizable electronic clinical research form inside SPE-type environment, and included both Windows and Linux Virtual Machines in a single SPE-type environment.
- Other key features of SPESiOR included: no need for fixed IP address in 12% environments, private cloud located in Finland in 24% environments, accessibility by users outside the managing organization in 35% environments, and possibility to add software in 59% environments.
- In many environments, operational reliability or timeline of customer service were not reported, i.e., service promise was missing.

CONCLUSIONS

- SPE-type environments have strategic differences and are aimed for different purposes.
- A key interest with them seems to be the possibility to collect new research data in structured form from patient charts, include machine learning or artificial intelligence, or extend existing structural data securely with control arm(s) or follow-up(s) as well as demonstrating the evidence as dashboard.

REFERENCE: 1) Soini et al. 2017, Clin Ther;39:537–557

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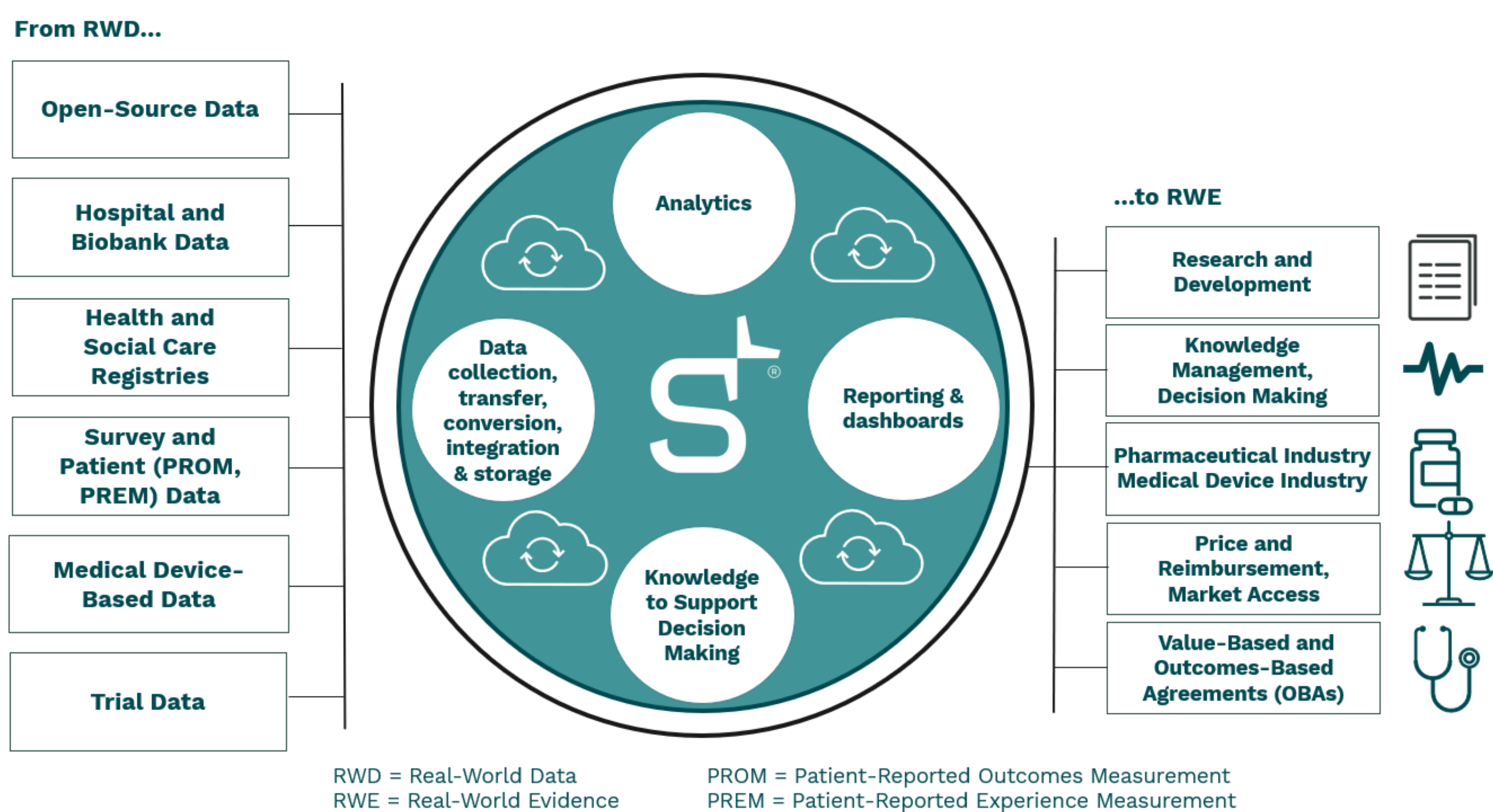


Figure 1. SPESiOR® secure processing environment.