

Global Data Privacy



Security and Risk Assessment in GDPR: from policy to implementation

Enisa Workshop

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Nicola Orlandi is currently the Head of Data Privacy Pharma in Novartis. In this role he's partnering with divisional business to enable growth, productivity and innovation, implementing privacy controls and considering data privacy requirements as well as business needs.

A new era for the use of health data

- ❑ The Health Care Sector is processing different categories of personal data and needs to increasingly use health data to improve patient outcomes
- ❑ Pharma is also accessing an unprecedented depth and breadth of health data



DIGITAL MEDICINE

**REAL WORLD
EVIDENCE**

SECONDARY USE

Digital solutions improve health outcomes for patients

CLINICAL TRIALS



Improvement of trial administration and enhancement of patient experience and outcomes

PATIENT EXPERIENCE



aid in patient care and help in identifying and delivering on big trends

PROVEN OUTCOME



Collaboration to drive continuous innovation from insights through the assessment of de-identified patient data

....with advantages for all stakeholders in the system

Patients

- More personalized treatment approach
- Better therapeutic outcome

Payers

- Enable outcome based pricing
- Verify cost offset across budget lines

Physicians

- Decisions supported by richer data
- Best practices identification

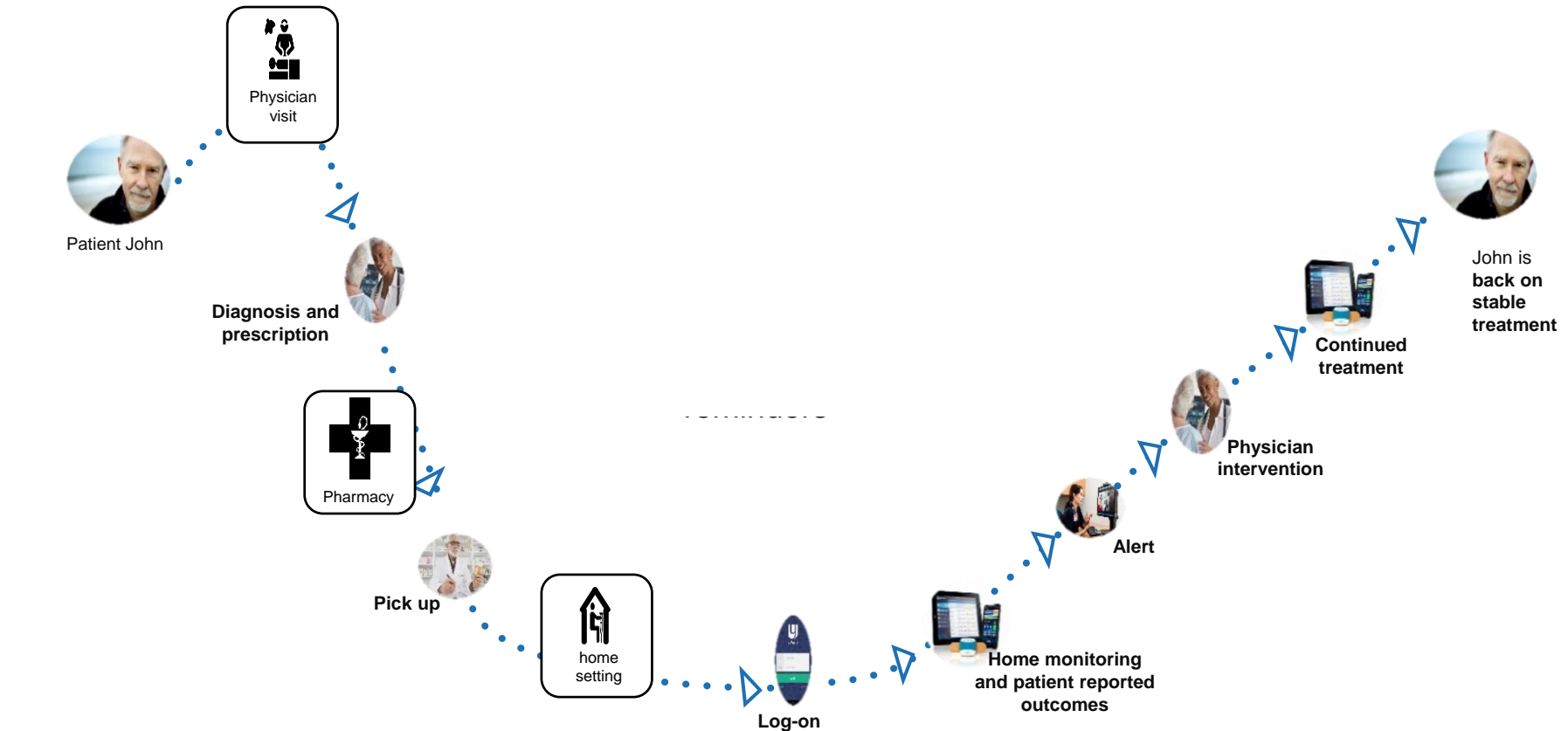
Scientists

- Identify new disease pathways
- Accelerate development of new therapies

Policy makers

- Reduce waste in the healthcare system
- More secure and sustainable healthcare

Beyond the pill – a new use of information will improve therapies



Solution Elements



Adherence/ side effect App



Sensor 2.0

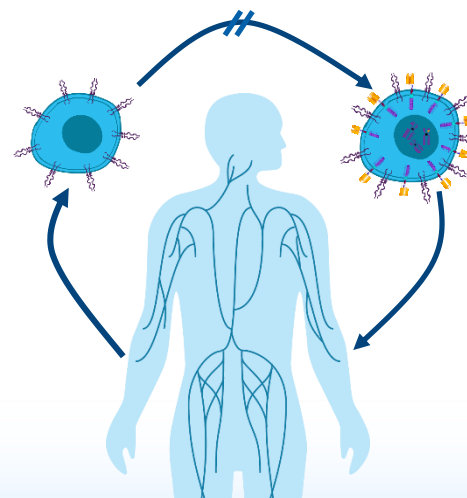


Artificial Intelligence algorithm

Autologous therapy and chain of identity

In an autologous immunocellular therapy, maintaining an accurate Chain of Identity is essential to patient safety.

Data Privacy plays also a relevant role when defining a proper measures creating a safe environment around patients' data.



autologous: cells or tissues taken from and returned to the same individual¹

Reference: 1. National Cancer Institute Dictionary of Cancer Terms.
<https://www.cancer.gov/publications/dictionaries/cancer-terms?CdrID=44912>. Accessed March 9, 2017.

Digital technologies and responsible use of health data...

Digital and new data sources: Social media, apps, websites, bl

Use of data:

- Scientific research

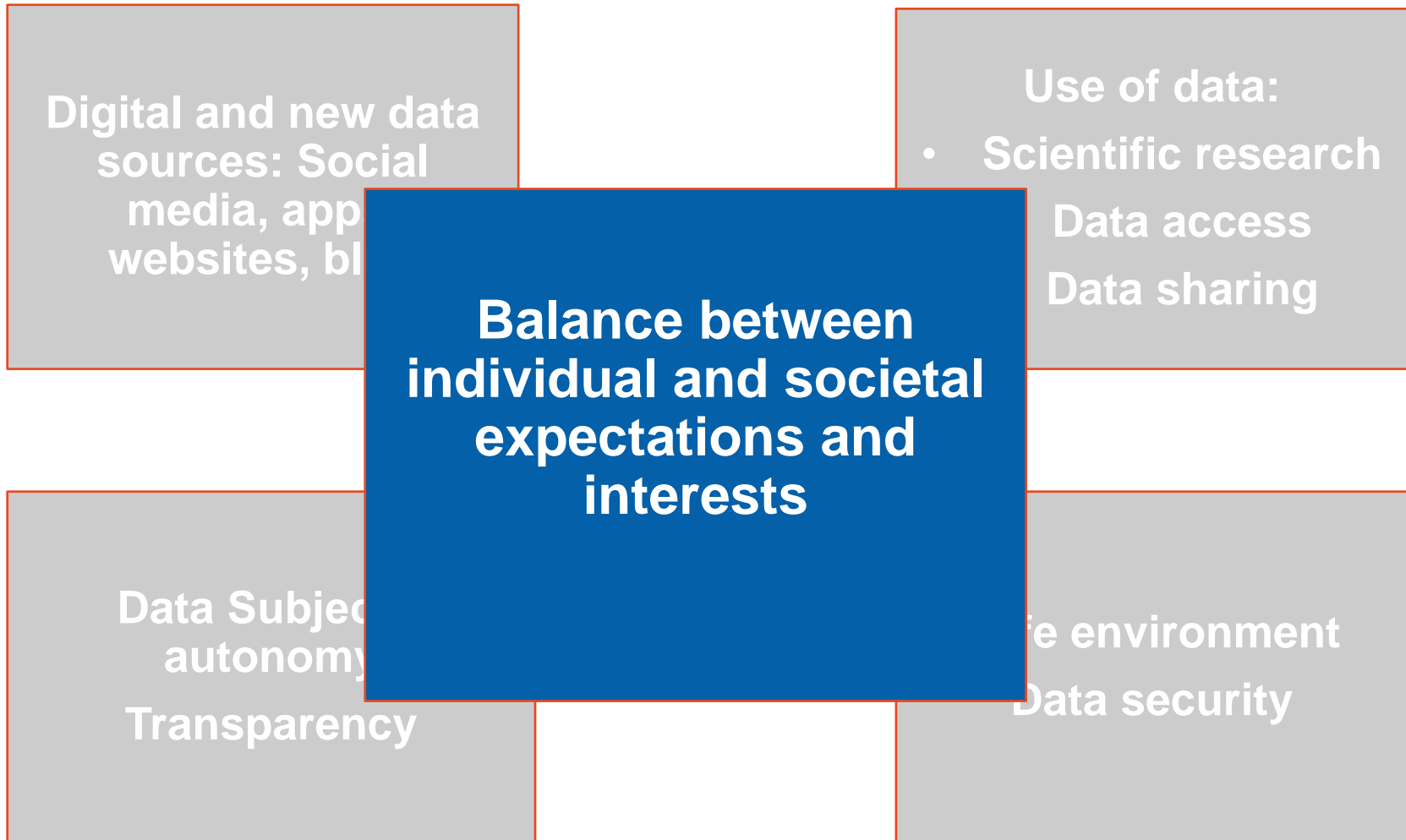
Data access
Data sharing

Transformation and opportunity

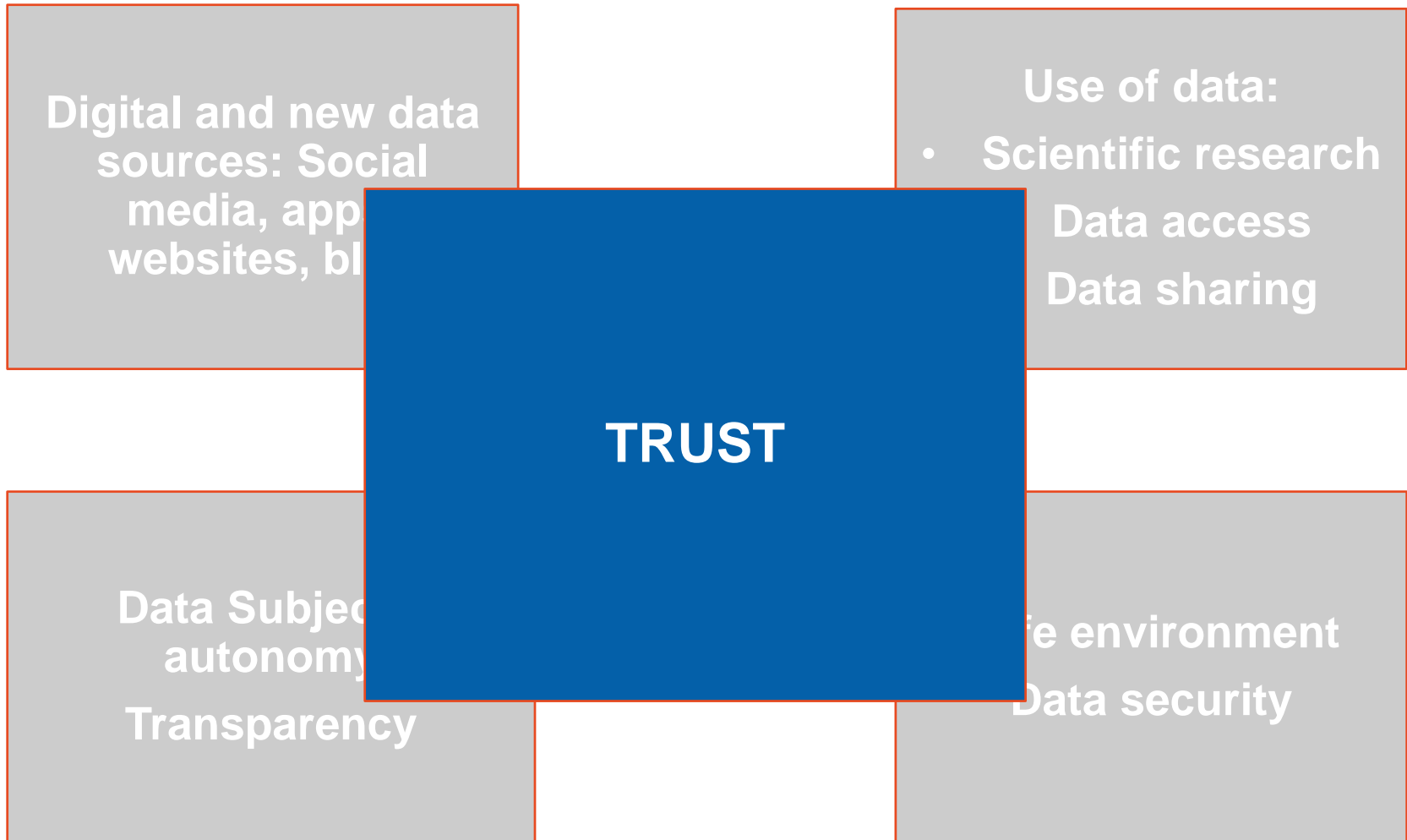
Data Subject
autonomy
Transparency

Safe environment
Data security

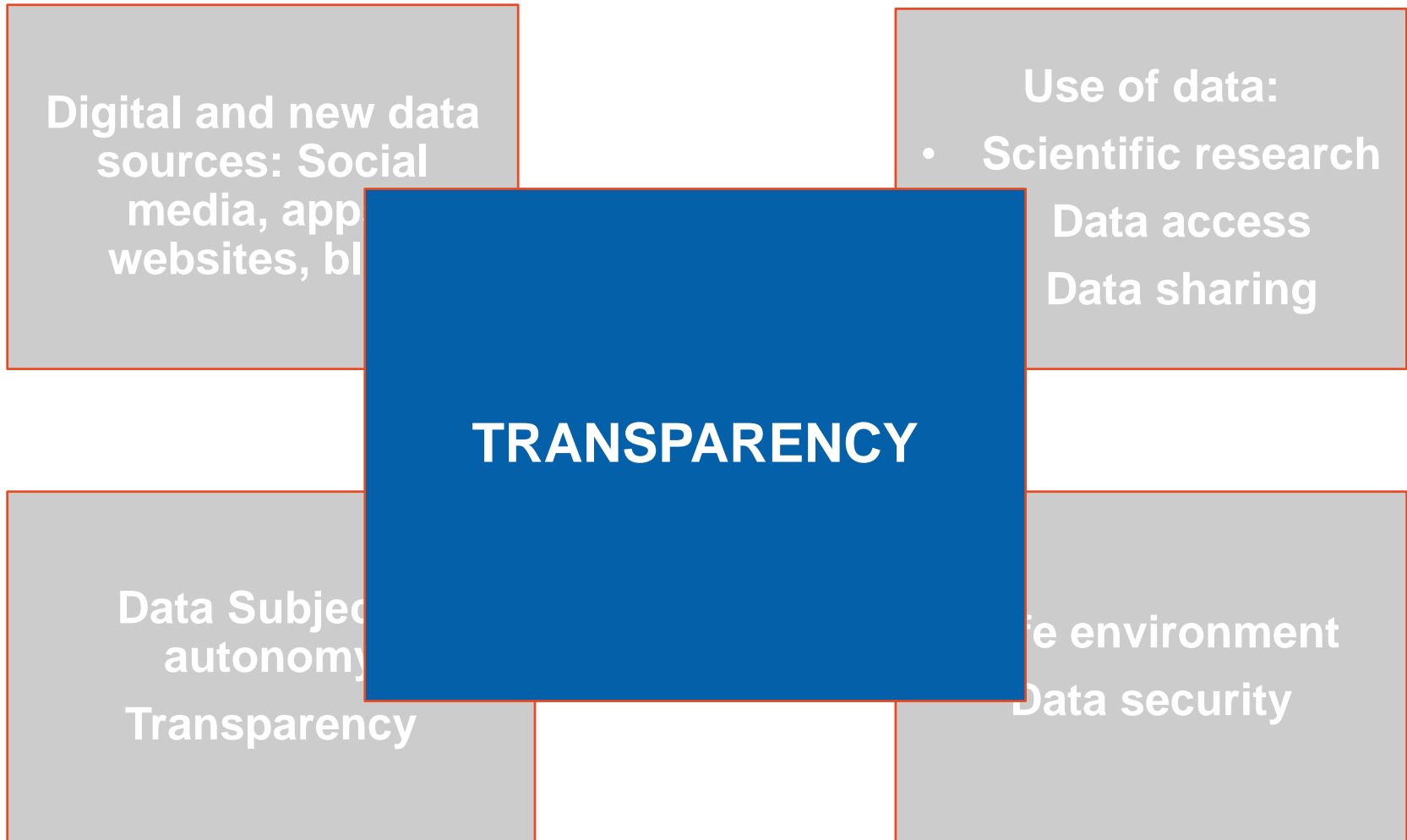
Individual and societal context



What do we need to build and demonstrate



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An holistic strategy and governance in line with GDPR rules will help to manage data properly....

Risk Assessment
Risk Management

Technical and
organizational
governance

- Enable responsible data use
- Create value from personal information and enable innovation
- Maintain public trust

Clear strategy, rules
and guidelines

Dedicated tool and
safe environment

....and will also support scientific research and further use of data

A transparent and reliable approach will also support further processing of health data for scientific research if a **dedicated governance is in place with appropriate safeguards:**

- technical and organizational measures (e.g. **pseudonymization**) protecting rights and freedoms of individuals and ensuring respect of the principle of data minimization